THE STATUS OF THE TECHNICAL INFRASTRUCTURE TO SUPPORT DOMESTIC FOOD IRRADIATION

HEARING

BEFORE THE

SUBCOMMITTEE ON
ENERGY RESEARCH AND PRODUCTION

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

NINETY-EIGHTH CONGRESS

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THE STATUS OF THE TECHNICAL INFRASTRUCTURE TO SUPPORT DOMESTIC FOOD IRRADIATION

THURSDAY, JULY 26, 1984

House of Representatives,
Committee on Science and Technology,
Subcommittee on Energy Research and Production,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:10 a.m., in room 2318, Rayburn House Office Building, Hon. Marilyn Lloyd (chairman of the subcommittee) presiding.

Present: Representatives Lloyd, Harkin, and Walker.

Staff present: Keith Jansen, William Harvey, Mr. Clement.

STATEMENT OF HON. MARILYN LLOYD, A U.S. REPRESENTATIVE FROM THE STATE OF TENNESSEE

Mrs. Lloyd. The Subcommittee on Energy Research and Production will come to order. I thank all of you who are in attendance today; I certainly appreciate your presence.

Before we begin I would like to ask unanimous consent that the subcommittee permit today's proceedings to be recorded and covered by the news media and other persons. Without objection, so ordered.

I would like to apologize for being late this morning. I think most people here, that attend this subcommittee's hearings, are usually quite prompt, so I do apologize for running a little bit late this morning.

I do wish you good morning, and today we will receive testimony from Government as well as private witnesses on the subject of irradiation technology and its application to food processing and other related industries.

A few months ago a major controversy erupted over the impending suspension of the use of the chemical ethylene dibromide [EDB] as a conventional method for controlling insect infestation in the food cycle. Similar concern has been expressed regarding the safety of other popular chemical treatments used in processing foods. I am acutely aware of the need to identify and develop safe and viable alternatives to food preservation. I share the concern of everyone, particularly the agricultural community, for providing adequate supplies of wholesome and nutritious foods for the American people.

Modern technology provides us with a potential option in the application of high-level energy sources which produce ionizing radiation. The irradiation process is one of the most studied technologies in the history of food processing, dating back to the 1940's. It received major emphasis in the Atoms for Peace Program of the 1950's and represents yet another shining example of the beneficial application of nuclear science. Research efforts over the decades, both domestic and international, have contributed to its evolution as a viable technology of diverse utilization. It is incumbent upon us to objectively assess how the development of this technology might further benefit our society as well as all mankind.

This technology, like all technology, must be properly applied to achieve its ultimate degree of safety and performance. There have been many barriers to overcome in arriving at our present juncture. The institutional and technical impediments are gradually being overcome. My colleagues and many business and technical professionals tell me that it is an idea that has truly come of age. Some say that this technology has the potential to completely revolutionize the food processing industry. On the other hand, there are a number of concerns about safety and public awareness and the projected economics for such widespread applications. There is a critical need to give this alternative a fair, as well as a judicious, review.

The remaining problems should be fully addressed and the attendant solutions thoroughly explored. Ultimately, we must determine what is the appropriate role for the Federal Government to assume in support of the research and development efforts required to adequately explore the full and realistic potential of this technology.

Today we will focus on the technology issues of irradiation, while maintaining a perspective on the many interrelated aspects downstream. We are very fortunate to have with us today a very distinguished group of experts in this field, and with their help, we will explore the issues related to legislative activity, Government as well as industry R&D, regulatory activity, international interest, industry needs, consumer concerns, commercial development, as well as other technical and institutional requirements.

It is indeed a pleasure to have this fine group of witnesses here today and we look forward to hearing what they have to say about these subjects.

[The prepared statement of Mrs. Lloyd follows:]

STATEMENT OF HON. MARILYN LLOYD

Good morning, ladies and gentlemen. Today we will receive testimony from government and private witnesses on the subject of irradiation technology and its application to food processing and other related industries. A few months ago a major controversy erupted over the impending suspension of the use of the chemical ethylene dibromide (EDB) as a conventional method for controlling insect infestation in the food cycle. Similar concern has been expressed regarding the safety of other popular chemical treatments used in processing foods. I am acutely aware of the need to identify and develop safe and viable alternatives for food preservation. I share the concern of everyone for providing adequate supplies of wholesome and nutritious foods for the American people. Modern technology provides a potential option in the application of high level energy sources which produce ionizing radiation.

The irradiation process is one of the most studied technologies in the history of food processing, dating back to the 1940's. It received major emphasis in the Atoms for Peace program of the 1950's and represents yet another shining example of the beneficial application of nuclear science. Research efforts over the decades, both domestic and international, have contributed to its evolution as a viable technology of diverse utilization. It is incumbent upon us to objectively assess how the development of this technology might further benefit our society and mankind.

This technology, like all technology, must be properly applied to achieve its ultimate degree of safety and performance. There have been many barriers to overcome in arriving at our present juncture. The institutional and technical impediments are gradually being overcome. My colleagues and many business and technical professionals tell me that it is an idea that has truly come of age. Some say that this technology has the potential to completely revolutionize the food processing industry. On the other hand, there are a number of concerns about safety and public awareness and the projected economics for such widespread applications. There is a critical need to give this alternative a fair as well as a judicious review.

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Mrs. LLOYD. Before we do begin, however, I understand that our ranking and our distinguished Republican member, Mr. Walker, does not have a statement to make at this time, but he wishes to have his statement included in the record at the appropriate time. Without objection, it will be included. We also have a statement from the ranking Republican member of this committee, the Honorable Larry Winn, who also wishes for his opening statement to be made a part of the record. Without objection, it will be made a part of the record.

[The prepared statement of Mr. Winn follows:]

STATEMENT BY THE HONORABLE LARRY WINN, JR.
SUBCOMMITTEE ON ENERGY RESEARCH AND PRODUCTION
FOOD IRRADIATION TECHNOLOGY HEARING
JULY 26, 1984

THANK YOU, MR. CHAIRMAN, FOR THIS OPPORTUNITY TO MAKE A FEW COMMENTS.

I HAVE NOTED THAT, IN ADDITION TO THE MEMBERS OF CONGRESS WHO ARE TESTIFYING, WE HAVE A GROUP REPRESENTATIVE OF ALL THE PARTICIPANTS IN THE NATION'S IRRADIATION PROGRAM. FROM THIS GROUP WE SHOULD BE ABLE TO GET A FAIRLY GOOD IDEA OF THE STATUS OF THE BROAD IRRADIATION PROGRAM, THE RESEARCH AND DEVELOPMENT REMAINING TO BE PERFORMED, THE PROMISES OFFERED BY IRRADIATION, AND THE IMPEDIMENTS WHICH HAVE BEEN AND MIGHT BE IMPOSED ON WIDER USE OF THE TECHNOLOGY.

REVIEW OF THE TESTIMONY PROVIDED BY SEVERAL OF THE WITNESSES RAISES A NUMBER OF QUESTIONS, SOME OF WHICH WE MAY HAVE ANSWERED TODAY. IN CASE THEY ARE NOT, I WOULD REQUEST PERMISSION TO SUBMIT THOSE QUESTIONS FOR ANSWER AT A LATER DATE. MENTION IS MADE OF PRIOR RESEARCH AND I WOULD LIKE TO KNOW SOMETHING MORE ABOUT THE SPONSORSHIP AND THE RESULTS FROM THAT ACTIVITY. A BIG QUESTION ARISES AS TO THE FUTURE SOURCE OF THESE GAMMA RAY-EMITTING RADIOACTIVE MATERIALS. IT IS SOMEWHAT UNFORTUNATE THAT WE DO NOT HAVE GREATER REPRESENTATION FROM THE INDUSTRIAL SECTOR SINCE THEY WILL EVENTUALLY DETERMINE THE EXTENT OF TECHNOLOGY TRANSFER.

MR. CHAIRMAN, IRRADIATION TECHNOLOGY IS A VERY INTERESTING SUBJECT. IT APPEARS TO OFFER A LARGE NUMBER OF BENEFITS TO MANY INDIVIDUALS AND INDUSTRIES. I HOPE THAT THIS HEARING WILL PROVIDE THE KIND OF INFORMATION WE NEED FOR PROPER OVERSIGHT.

THANK YOU.

Mrs. **Lloyd**. We are very fortunate to have with us today my distinguished and honored colleague who came to the Congress with me in 1974, and has served the Congress well, and I certainly value his friendship. Congressman Tom Harkin is also the chairman of the House Agriculture Subcommittee on Livestock, Dairy, and Poultry, as well as a very valuable member of this committee.

Tom, we're awfully happy to have you here today and we regret that you're going to leave us; we think it's a bad decision to leave us and join the other body, but that's a decision you have to make for yourself. [General laughter.]

But I do want to say, Tom, that we're happy to have you here today and we welcome your opening remarks.

STATEMENT OF HON. TOM HARKIN, A U.S. REPRESENTATIVE FROM THE STATE OF IOWA

Mr. **Harkin**. Thank you very much, my esteemed colleague from Tennessee, Marilyn Lloyd. I want to congratulate you and thank you for having this very timely hearing; and I also want to thank you for your leadership in this area. One of the consoling thoughts that I have in leaving this body and—hopefully—going to the other one, is that I leave it in the good hands of individuals like Marilyn Lloyd. We have served together on this committee and on subcommittees of this committee since 1975 and I can't think of an individual for whom I have a higher degree of respect and friendship than my colleague from Tennessee. She is a true battler for the things that she believes in. She's very effective and is able to get things done, and I don't think a higher accolade could be given to any Member of Congress than to say that you're effective and get things done. And you have, Marilyn, and I just want to tell you how pleased I have been over the last 10 years to have served with you on this committee and subcommittees of this committee, and I know that we will do a lot of work together in the future, too.

Mrs. **Lloyd**. Thank you very much, Tom, and we are looking forward to working with you as you move to the other body.

Mr. **Harkin**. Thank you.

You know, Marilyn, I first became aware of this irradiated food on the Agriculture Committee several years ago when the Department of the Army brought some food to us that had been irradiated several years before. If I remember right, I ate some lunchmeat or something like that that had been irradiated—oh, I don't know how many years—10 years before, and it was just put on the shelf, and I found it very pleasant and tasteful. And as you can see, I'm still in pretty good shape today; didn't hurt me a bit, and that's been about 7 years ago.

I became very intrigued by the whole process of irradiation and have followed it very closely since; and so, like I said, I'm very pleased that you're taking a leadership role in this.

The preservation of food is expensive, and the amount that's lost in our society is very huge. Food irradiation is a technique which can go a long way toward solving both of these problems.

There has been a lot of talk about consumer reaction to this, but a large portion of American families use microwaves to heat their foods; they've been doing it for many years. Irradiation is not the same, but it's a similar kind of process; they both simply are types of energy applied to the food, and in both cases the source of the energy does not remain in the food, only the effect remains.

The food itself does not emit any of that absorbed energy.

When microwaves excite the molecules in the food causing heat, the food is cooked. When food irradiation is applied, little heat is produced; and thus, generally, there is relatively little change in the flavor or odor and there is little loss of nutrient value. What happens is that the irradiation disrupts the chemical bonds, thus killing off microorganisms and insects.

I think it is quite clear that the use of irradiation is an excellent procedure and can gain wide public acceptance compared to the alternatives that are currently used.

Unfortunately, food irradiation faces a number of regulatory hurdles. A number of them are resolved by Congressman Sid Morrison's bill, H.R. 5605, and I see our colleague is here with us today, a bill which I am pleased to have cosponsored.

As you know, Madam Chairman, one of the problems is that the FDA considers the use of irradiation as an additive rather than a process and, naturally, that is a big stumbling block. One of the things that we have to do is to get them to look at it as a process rather than as an additive to the food, because it isn't an additive. There's nothing left in the food to consider it an additive.

This hearing, Madam Chairman, as you said, will allow us to hear from the FDA, the Department of Agriculture, Energy, and the Nuclear Regulatory Commission—all of whom have regulatory concerns—and also we'll hear from the private sector, as well. I hope this hearing will provide a stimulus to all of the agencies to focus their attention in a concerted effort towards this important area and to speed the process of providing workable rules that will allow for the smooth commercialization of this technology.

I am pleased that the FDA has issued rules allowing for the irradiation of spices, and I hope they move quickly on the applications before them for other food products.

Of course, Madam Chairman, I am most interested in the irradiation of pork. That stands to reason since I am from Iowa, and in Iowa we produce 25 percent of all the pork in this country. We can have, as the National Pork Producers Council has pointed out, 100 percent guaranteed trichina-safe pork with the use of low levels of irradiation, far below the 100 kilorad level that the FDA has proposed in these draft rules.

Work at Iowa State University has shown that there is no deterioration for pork that has been irradiated; if anything, perhaps even a slight improvement because of the loss of some microorganisms, even at low radiation levels.

Eventually, irradiation can dramatically improve our ability to preserve food products over a long period of time. While the FDA is considering the approval of irradiation of food below the level of 100 kilorads, the World Health Organization has approved for international commerce a radiation as perfectly safe at 10 times that level.

Eventually, pork irradiation at higher levels can result in a substantial increase in our export market, and I guess that's what I really want to concentrate a few of my remarks about. We have expanding markets taking place all over the Third World. We always tend to look at the markets in the industrialized nations—Japan, Europe, Canada, those countries—and we tend to not look at the potential increase in our export markets in the Third World. But those markets will develop, and they will be there in the next 10, 15, 20 years. We ought to be taking the lead in developing those markets and getting into those markets right now. Of course, one of the reasons we can't ship some of our value-added products to those countries is because of the lack of refrigeration and storage facilities that they have in those countries.

Irradiation is one way, and I think the best way, that we can make two things happen. One, we could develop markets in those countries for our processors, for our farmers in this country; and second, we can give them the high protein, the meat, and meat products that they can use in those developing countries, and which they want and which they need. It all boils down to whether or not we're going to ship our raw materials out or our value-added products. We can value-add to our meat, to our meat products, and I believe we can develop these markets in the developing countries of this world.

And so, Madam Chairman, I would say that this hearing is an important step in our advancement in this critical area; and again, I want to thank you for having this hearing.

I would just like to ask, Madam Chairman, if I could place into the record the statement of the National Pork Producers Council on the issue of irradiation of pork, and also portions, Madam Chairman, of this report—it's a consumer reaction to the irradiation concept, a summary report put out by the U.S. Department of Energy By-Products Utilization Program. There are some portions in there——

Mrs. LLOYD. Without objection, Tom, both reports will be made a part of the complete record, and I share with you that there will be a value that we compile with studies in this testimony, in this hearing. [See appendix.]

Thank you very much for your input. We appreciate it.

Mr. HARKIN. Thank you, Madam Chairman.

[The prepared statement of Mr. Harkin follows:]

OPENING STATEMENT

Congressman Tom Harkin

Hearing on Food Irradiation

Subcommittee on Energy Research and Production
Science and Technology

July 26, 1984

I would like to thank Congresswoman Marilyn Lloyd for holding this hearing which will allow the Committee to examine this important issue.

The preservation of wholesome food is expensive, and the amount that is lost is huge. Food irradiation is a technique which can go a long way towards solving many of these problems.

A large portion of American families use microwaves to heat their foods. They have been doing so for years. Irradiation is a similar process. They are both simply types of energy applied to the food. In both cases, the source of energy does not remain in the food. Only the effect remains. The food itself does not emit any energy.

When microwaves excite the molecules in the food causing heat, the food is cooked. With food irradiation little heat is produced. Thus, generally, there is relatively little change in the flavor or odor. And, there is little loss of nutrient value. What happens is that the irradiation disrupts the chemical bonds, thus killing off microorganisms and insects.

I think it is quite clear that the use of irradiation is an excellent procedure and can gain wide public acceptance compared to the alternatives that are currently used.

Unfortunately, food irradiation faces a number of regulatory hurdles. A number of them are resolved by Congressman Sid Morrison's bill (HR 5605) which I am pleased to have cosponsored.

This hearing will allow us to hear from the Food and Drug Administration, the Department of Agriculture, the Department of Energy, and the Nuclear Regulatory Commission — all of which have regulatory concerns — and from the private sector as well. Hopefully, it will provide a stimulus to all of the agencies to focus their attention towards this important area and to speed the process of providing workable rules that will allow for the smooth commercialization of this technology.

I am very pleased that the Food and Drug Administration has issued rules allowing for the irradiation of spices and I hope that they move quickly on the applications before them for other food products.

I am most interested in the irradiation of pork. We can have 100 percent guaranteed trichina-safe pork with irradiation. That can be accomplished at low levels, far below the 100 kilorad level that the FDA has proposed in draft rules.

Work at Iowa State University has shown that there is no deterioration of taste for pork that has been irradiated. If anything, there is a slight improvement because of the loss of some microorganisms even at low irradiation levels.

Eventually, irradiation can dramatically improve our ability to preserve our food products in a safe way over a long period of time. While the FDA is considering the approval of irradiation of food below the 100 kilorad level, the World Health Organization has approved irradiation as perfectly safe at 10 times that level.

Eventually, pork irradiation at higher levels can result in a substantial increase in our export market.

Irradiation will be of great benefit to the consumer in the United States. And, it will be even more important in those parts of the world which lack adequate refrigeration.

I believe that this hearing is an important step in our advancement in this critical area.

Mrs. **Lloyd**. We are happy now that the ranking Republican member of this subcommittee, the Honorable Bob Walker, is with us today. Bob, we have a permission for your opening statement to be included in the record. We're happy that you are here, and you certainly provide us very valuable input in our hearing.

STATEMENT OF HON. ROBERT S. WALKER, A U.S. REPRESENTATIVE FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. **Walker**. Thank you, Madam Chairman. I just want to say that I appreciate the fact that you're holding the hearings. There is no doubt that the food processing industry is extremely vital; we all know the major impact that our entire agricultural industry, agribusiness, makes in our economy as a whole, and one of the issues of the future is the question of how we do appropriate processing? What are the future technologies that are available to us?

I think, through this series of hearings, you are opening the door to public understanding of some of the things that may be available to us so that we may be able to proceed forward with far more public understanding and far more ability to enact some of these new technologies. I'm very pleased to join with you in welcoming colleagues who have taken a particular interest in this subject, such as Mr. Harkin, Mr. Watkins, who will testify, and Mr. Morrison from Washington who will testify. All of them have shown real leadership, and this is an opportunity for them to demonstrate that this is something that has had a good deal of thought here on Capitol Hill.

Thank you, Madam Chairman.

Mrs. **Lloyd**. Thank you very much, and I know that everyone here shares with us the feeling that this is a new dimension in food processing and preservation, and I think it is certainly worthy of our attention today.

We couldn't start off with better witnesses than we have today, also. Our good friend, Wes Watkins from Oklahoma, is here. We certainly look forward to hearing from you today, Wes, and let me say before you begin, and for all that follow after you, if any of you who testify today prefer to summarize, please be assured that your entire statement will be made a part of the record; so you can go as you wish; whereas without objection, I would like to include for the record statements that have been received that Mr. Harkin referred to.

Welcome, Wes.

STATEMENT OF HON. WES WATKINS, A U.S. REPRESENTATIVE FROM THE STATE OF OKLAHOMA

Mr. **Watkins**. Thank you, Madam Chairman, and members of the committee——

Mrs. **Lloyd**. Excuse me just one minute, Wes.

Mr. **Harkin**. Wes, if you will yield just a second, I'm sorry but I have to go to my Livestock, Dairy, and Poultry Subcommittee, and I don't want to leave without——

Mr. **Watkins**. You're going to miss some good testimony.

Mr. **Harkin**. I know it. You always give good testimony, Wes. [General laughter.]

But really, I never knew about using it for green hides. It's really interesting.

Mr. WATKINS. It's pork and in the livestock industry—we ship all our hides out and forget the salt, and——

Mr. HARKIN. I just want you to know I read it, anyway, beforehand.

But, Madam Chairman, thank you. I just wanted to tell you that I am sure I can speak on behalf of all the Republican and Democratic members of the Livestock Subcommittee in saying we should move ahead on this.

Mrs. LLOYD. We thank you, and we are very pleased with your enthusiasm.

Wes, you're known to be a very practical member of this body, so I don't think you're going to come to us with any way-out ideas today. Please proceed.

Mr. WATKINS. Thank you. I appreciate that, and I hope my constituents back home hear that.

Mrs. LLOYD. If you want me to go out there and tell them, I will.

Mr. WATKINS. All right.

Madam Chairman, members of the committee, I'd like to say that I'm glad to return to the Science and Technology Committee. As some of you know, I spent 4 years here on this committee and I enjoyed it very, very much, and I still have a deep interest in what happens. I think that you're breaking the ice and breaking ground, so to speak, on a lot of new direction and research and technology, and I'm very happy to be here today to testify. I do ask that my testimony be accepted in full. I think we produced 135 copies of it last night; I was asking staff, "Why so many?" but I understand they have a lot of people interested in this subject.

I also want to ditto what our colleague, Congressman Harkin, said about our other colleague, Congressman Sid Morrison's bill, H.R. 5605. I'm a cosponsor of that bill. I know he will explain it in great detail, so I will not go into it except to say I think Congressman Morrison's bill is on the right track, the right direction for us to move this country ahead.

Madam Chairman, I come here, yes, as a member of this body; but probably, professionally, before coming here in my schooling—I'll put it that way—I was in agriculture. I went to Oklahoma State University in the College of Agriculture. Needless to say, we have done a tremendous job in the production of agriculture in America. We have taken the technology; we have utilized it; we have produced.

I think that if we observe and analyze, we have not kept up in the marketing of our agricultural products in the technology that's necessary to do that, as we have in the production. We produce, but many times—there are a lot of variables, I know—but the technology that we have had at our fingertips we have not been able to initiate, we have not utilized.

I come today whole-heartedly endorsing the irradiation process, mainly from one major factor; and that factor, if nothing else, should take us to have a keen look, and that's the balance of trade. Agriculture is a product that we produce in abundance and it's unfortunate that we're not exporting a greater abundance of that to many other Third World developing countries and many other areas that are faced with world hunger. One of the great problems that we have is being able to market it or be able to enter that trade.

Madam Chairman, members of the committee, in 1984 we had a trade deficit of $126 billion, twice as large as 1983. We haven't had a positive trade balance since 1975. Now, everyone knows that agricultural commodities have been the mainstay of our export trade; but the value of our agricultural exports have slipped the past 2 years. Irradiation can help us increase our agricultural exports. At the same time, it can help us decrease our imports of finished leather goods. Those are the two subjects I want to summarize in my testimony here today.

First, on the irradiation of fruits and vegetables, countries importing our fruits and vegetables have three concerns, Mrs. Lloyd and members of this group, they have three concerns about our products: the residue of chemicals and pesticides and the possible introduction of new pests into their land. These current concerns have led to restrictions on commodities treated with certain chemicals and pesticides, and quarantines of imported produce to protect against introduction of these pests.

I just took my family to California for the convention, and I went through that quarantine checkout in California. California has a concern on what's shipped into that particular State, so you can see why many countries have a great concern.

With some additional research and acceptance of irradiated foodstuffs, irradiation could replace or greatly reduce the use of chemicals and pesticides, not only on our exported products but those products that have become of great concern in this country. As you well know, as you read the current articles that are coming out, EPA is putting quarantine on this and quarantine on that, that the farmers cannot utilize—and they are confronted with a real problem of how to produce in soils that have become contaminated, not the virgin soils where they don't have that particular problem with pesticides.

Irradiation has also been shown effective in eliminating those pests which might accidently be shipped in from foreign countries. The USDA is currently conducting tests which show irradiation of citrus, primarily grapefruit, as an alternative to treatment EDB, which has been banned, and more cost-effective and energy-efficient than other alternatives to EDB, which happen to be cold storage and vapor heat treatment. It's much more cost-effective.

Irradiation was also used, on a conditional basis, during the 1982 California infestation of Mediterranean Fruit Flies.

U.S. research into irradiation as an alternative to pesticides has been or is being conducted on the Codling Moth and apples, the Mexican Fruit Fly and the Caribbean Fruit Fly and grapefruit. Low-dose irradiation has been shown to be an effective pest control in such commodities as tomatoes and cucumbers; but in our country, until recently, irradiation has only been approved for sprout areas in potatoes and insect infestation of wheat flour. Foreign governments are looking to us to take the lead in this area.

Irradiation has also been proven to be effective to preserve fresh produce. This is a staggering figure: Currently, 30 percent of fresh produce is lost to spoilage. As Tom said a while ago, our Astronauts eat irradiated food; I think many of us on this Committee of Space Science realize how important exploration is. Our Astronauts consume irradiated food in outer space.

Mrs. **Lloyd**. This type of spoilage is a luxury that we can no longer afford or can look to afford in the next decade.

Mr. **Watkins**. That's correct. And you think about what we could do in the Third World developing countries and in hunger—even in hunger in this country—if we're going to lose that quantity to spoilage, that's a loss, zero, no income. We could utilize that food for peace, in our commodity programs—there are a great number of other countries, Mrs. Lloyd, that have led us, led the United States, in irradiation, in using it to preserve fresh strawberries in Belgium, potatoes in Japan, rice pudding in Russia, also onions in France—these are all being preserved by irradiation. And 28 countries have already given unconditional or provisional clearance for commercial irradiation of a lot of their foodstuffs.

The GAO report says the United States could have saved $18 million—talking about saving money—the United States could have saved $18 million in 1968 alone if the meat consumed by the soldiers in Vietnam had been irradiated rather than frozen. Many foods are too perishable for reaching certain markets or are carriers of insects which create a problem.

I want to mention one other area of irradiation—as Congressman Harkin said, irradiation of green hides. The U.S. tanning industry has taken a back seat to foreign competitors. Fully 60 percent of hides produced by domestic slaughter are being exported. I come from cattle country; the hides make up about 10 percent of the value of that animal. We export those hides. From an environmental problem—because of all the salt they have to use to preserve those hides, we end up shipping them to tanneries, and our domestic tanneries, Mrs. Lloyd, are closing their doors. So we're talking about economy for our country, the building of jobs in our country. Imports of leather and leather products increased 12 percent in 1983 to $5.1 billion. Horsehide has been the domestic, nonrubber footwear. The import market share of products surged, and we have a great problem there.

Now, we are reverting to colonial status in the leather industry. In effect, we're snipping out the raw product, as Mr. Harkin said, the hides, and import the finished products. We're exporting our jobs, so we're talking about a job development phase of this program, too. The reason for this is the decline of the domestic tanning ~~industry.~~ This industry has been strapped with strict environmental controls on the disposal of salt and other products in the tanning process. The answer to this problem, in my opinion, is not relaxing the environmental controls but coming up with innovative processes to tan the hides, and I think irradiation is that answer.

Mrs. **Lloyd**. Excuse me, Wes. Would this also be of benefit to our ailing shoe industry as well?

Mr. **Watkins**. You'd better believe it, Mrs. Lloyd.

Mrs. **Lloyd**. I wouldn't doubt that this would be maybe the most labor-intensive bill that this subcommittee has considered for a long time.

Mr. **Watkins**. That's right. It is a job bill. If you save dollars on one end of the raw product, even if the labor costs are a little bit more, you've offset some of it on the other end, which makes it a competitive product. And in the free enterprise private sector, you've got to have a competitive product, and I think this would put us in more of a competitive position in this country. So I think it's very much—I think the Speaker of the House should be interested in this type of legislation because there's a lot of that type of leather industry up in that part of the neighborhood.

Now, what is needed? DOE, through its Defense Nuclear Waste Management, has taken the lead of commercialization of irradiation. DOE believes that it can demonstrate the commercial viability of this product and that industry will assume operation of demonstration projects in commercialized irradiation. DOE has been authorized to construct the demonstration irradiators, one for municipal sludge in New Mexico, one for citrus in Florida, one for pork products—probably in Ames; as Mr. Harkin said, they've had a pioneer interest in this—and a portable irradiator which will initially concentrate on Codling Moths and apples. And this demonstration irradiator, in my opinion, should be built for fruits and vegetables and green hides. This should be a commercial scale-sized, allowing for both research into commercial operation.

The Energy and Water Development Appropriation Subcommittee that I serve on, the Energy and Water bill that just passed the Congress, was recently signed by the President 10 days ago, directs DOE and USDA to conduct a joint study into the design of an additional irradiator for produce and green hides. If that study is positive, and I think it will be, I will expect to come back and ask you, Madam Chairman, to allow me to come back to appear before you next spring and seek authorization for construction of that irradiator.

But we must get on with the commercialization of irradiation. Our trade deficits, our jobs demand it.

I'd like to close by making a quote from Willard Libby. Willard Libby, the late Nobel Peace Prize winner, warned a few years ago.

> The millions who live in the shadow of starvation deserve the benefits of a more rapid introduction of irradiated foods. Wasteful as man has been in the past, he can no longer afford to waste time, technology, and food.

I think that sums it up.

[The prepared statement of Mr. Watkins follows:]

STATEMENT OF HON. WES WATKINS, A REPRESENTATIVE FROM THE STATE OF OKLAHOMA

Madam Chairman and Members of the Subcommittee, I appreciate the opportunity to appear before you today to address a subject which I think is of vital importance to the future of the nation. However, I must first lay the framework.

I have introduced a bill calling for a White House Conference on International Trade to provide a constructive program to reverse trhe United States' continuing devastating trade deficits. Commerce Department figures indicate that the trade deficit for this year will be $126 billion dollars, twice as large as 1983, which itself was a record year. Since 1980, there has not been one quarter in which the United States showed a positive trade balance, an event which last occurred in 1975. Further, part of another piece of legislation I have proposed would allow the Secretary of Agriculture to utilize the amount of money now being expended to store, maintain and transport surplus agricultural commodities (plus the cost of interest on money supporting agricultural programs)- to subsidize agricultural exports. The United States is the only major agricultural trader nation not subsidizing exports.

The point is that I, along with a number of our colleages and others, are deeply concerned about this nation's ability to sustain trade deficits nearing the total of the domestic budget deficits.

A part of that trade deficit is being offset by agricultural exports which are made possible by the unsurpassed production capacity of America's farmer who feeds himself and 73 other people throughout the world. But, in recent years, even agricultural exports have declined from the bounty we had a few years ago. Yet, paradoxically, agriculture is part of both the solution and the problem of trade deficits, for we are doing a good job, but we could be doing better.

A part of the problem is evidently an unwillingness of some countries to accept food stuffs with the potential of chemical or pesticide residues or those which might introduce into a country a pest which could be devastating to crops not previously subjected to that particular pest. Spoilage before distribution to the ultimate consumer is a problem. Another part of the problem is that hides, a by-product of the domestic cattle industry accounting for nearly ten percent of the total value of the animal, are being exported only to return to our shores in the form of finished leather products, with a corresponding loss of domestic jobs and value-added increase.

It is my contention that with proper research, design and construction, with due regard for all aspects of health and safety, the irradiation process can help us do a better job in agricultural exports and thereby help reverse the horrendous balance of trade deficits.

And that's what I want to discuss with you today.

Exactly what is irradiation of food? The process uses ionizing radiation to preserve food. Preservation by this process can be achieved through the destruction of larval and adult forms of insects as well as the destruction of micro-organisms which are involved in food spoilage. Irradiation works by disrupting the organic processes that lead to food decay. With rays beamed from radiation sources, insects can be killed, along with bacteria, germs, fungus, molds, worms and other potentially damaging micro-organisms. An advantage to using this radiation to fight these destructive agents is that discarded nuclear wastes are recycled.

Then the question arises, how safe is food treated with radiation? The product, which does not become radioactive, is safe to eat and remains fresh longer. The wholesomeness of irradiated foods has been studied very thoroughly, not only from the toxicological but also from the chemical, nutritional and microbiological aspects. Much research has been carried out in these areas for almost 30 years in laboratories all over the world to evaluate any conceivable risk.

Irradiation does not make an initially good quality food even better. It does however, in some instances improve quality characteristics. For example, irradiation can improve the baking qualities of wheat flour. It can make meat more tender. It can reduce the rehydration time of dehydrated vegetables and can increase juice extraction from some fruits. And of course it improves the hygienic quality of the food by reduction or elimination of pathogenic bacteria or parasites or the replacement of a chemical used as a preservative or pesticide, whose residue in a food imposes a potential health hazard for the consumer.

Irradiation exposes food to gamma rays from a cobalt-60 or a cesium-137 source, or to high-energy electrons emitted by an electron accelerator. A major advantage of its use is that food can be packaged either before or after treatment. A particular attraction is radiation's ability to double the shelf life of fresh produce of which about 30 percent is currently lost to spoilage in the United States. Moreover, radiation-processed foods retain more of their original appearance, taste and texture than canned, heat-treated foods.

The Food and Drug Administration (FDA) has published proposed rules in the Federal Register which would permit the use of low-dose irradiation (below 100 krad) of foods without requiring prior approval.

Without an alternative to EDB, our farmers will suffer in the world marketplace. Many countries that import agricultural commodities from other parts of the world develop and enforce quarantine regulations. These regulations are designed to prevent the entry of undesirable pests into their agricultural production areas. Infestation by alien pests would reduce crop yields, require pest control programs, and result in marketing constraints which would negatively affect the economic base of the agricultural programs in these countries. Similarly, quarantine requirements imposed by individual U.S. states can restrict the interstate shipment of various agricultural commodities. Obviously, international acceptance of irradiated agricultural commodities without quarantine would do much to expand markets for American farmers.

Federal agencies involved with the issues of food irradiation consist of the Departments of Agriculture, Defense, Energy, and Health and Human Services.

The United States has conducted an intensive irradiation research program since the end of World War II. Funded primarily by the Army, but with strong support from the former Atomic Energy Commission, the Department of Energy and the Department of Agriculture, this research and development effort has been centered at the Army's laboratory at Natick, Massachusetts. This study has since been switched to the USDA facility in Philadelphia.

Foreign governments have been waiting for the United States, the acknowledged leader in the nuclear field, to point the way in the application of this new technology.

Currently, research is being conducted at various locations around the country for the codling moth in apples, the Mexican fruit fly and Caribbean fruit fly in grapefruit. Also, low-dose radiation can be used for pest control in such commodities as tomatoes, cucumbers and papayas. The list continues to grow as more research is done.

In Florida, USDA is running pilot projects irradiating citrus, primarily grapefruit, to control pests and as an energy-efficient alternative to cold storage and vapor-heat treatment once EDB is completely banned. In 1982, irradiation was used on a conditional basis in California as part of the fight against the Mediterranean fruit fly then threatening to devastate the state's produce crops.

American scientists pioneered the technology of food irradiation in the 1940's and the government first approved a limited use for potatoes and wheat flour in the 1960's. Today only irradiation for the sprout inhibition of potatoes and insect disinfestation and wheat flour are approved.

Fresh strawberries in Belgium, potatoes in Japan, rice pudding in Russia, papaya in South Africa, onions in France -- all are part of an expanding worldwide menu of foods preserved by radiation. So far, 28 countries, including Japan, Israel, France, Holland and the Soviet Union, have given unconditional or provisional clearance for the commercial irradiation of more than 50 foodstuffs, including vegetables and fruit. About 100 food irradiation plants are operating worldwide.

Astronauts aboard the recent Columbia Space Shuttle flights dined on meals that had been irradiated. My colleagues, now is the time to bring this project closer to home.

Economically, irradiation is our answer. The General Accounting Office, which reviewed the Army's pilot program, found that the U.S. would have saved about $18 million in processing, distribution and storage costs in 1968 alone if the meat consumed by soldiers in Vietnam had been irradiated instead of frozen. Business Week has noted irradiation is about 70-80 percent less expensive than canning.

Market enlargement for our farmers' production is probably the most significant potential benefits of food irradiation. It can have meaning locally, within a nation, or internationally. Many foods are too perishable for reaching certain market areas or are carriers of insects and pathogens which are restricted by embargo or quarantine. Irradiation can overcome such obstacles to product movement into new market areas.

That is my primary interest. Even the with production of new crops in economically depressed rural areas, without a market for these products our efforts will be in vain. Production is not our problem there, and the plight of the American Farmer today is not caused by lack of production capability -- on the contrary, America's farmers can and do out-produce the world. Irradiation can be the key to expanding our markets both locally and abroad. Having an irradiator associated with an agriculture research facility will be a big step toward making that happen. Let's help improve the lifestyle of these and similar rural Americans and at the same time change the balance of trade in our favor.

Willard Libby, the late Nobel Peace Prize winner, warned a few years ago, "The millions who live in the shadow of starvation deserve the benefits of a more rapid introduction of irradiated foods. Wasteful as man has been in the past, he can no longer afford to waste time, technology and food."

The second issue I will address is use of irradiation to treat green hides. Oklahoma cattlemen have long been a major influence in production of beef for the U.S., but yet we do not have a major commercial tannery to absorb the vast amount of hides. Surrounding states have a similar problem. The cost of setting up a tannery along with the problem of disposing of waste materials used in the process has discouraged new industry. Last year, we shipped almost one-half million hides out of the state for processing. Not only does this mean a huge transportation cost from the processing plant to the tannery, but this means a loss of revenue for an already low income area of our state and the nation, for the primary threat is not from domestic competition, but from foreign competitors.

Lacking innovative procedures and burdened by increasingly stringent environmental regulations, the domestic tannery industry has taken a back seat to foreign competitors. With EPA cracking down on tannery discharge levels, many plant owners have opted to cease operations rather than make modifications. One Oklahoma leather goods manufacturer said a Pennsylvania tannery he dealt with for years closed its doors due to environmental regulations.

Tannery plants discharge high levels of salt and chromium produced when hides are treated to make raw leather. Packers apply salt to preserve hides before shipping to tanneries. Tanneries wash that salt from the hides and some use chromium applications in the preservation process.

Most tanneries in the United States are located on the east and west coasts, far away from major packing plants. The logistics make shipping costs high. The tanning industry is looking for ways to reduce the cost of curing green hides in this country and ways to reduce the the pollution problem.

Since the number of tanneries in the United States is declining, domestic demand for raw hides has lowered, leaving the door open to foreign competition. The lack of domestically produced raw leather has impacted virtually all industries using leather. Domestic sources are becoming scarce and industries using leather are looking to foreign producers for their supplies. Cheap foreign labor is enabling the competition to outbid the domestic tanneries for the raw hide.

In 1983 Japan, Republic of Korea, Taiwan and Mexico were the largest importers of U.S. raw and cured cattlehides. Japan is now the biggest buyer of hides from American cattle. It purchases 60-65 percent of the available output annually. Taiwan took almost 10 percent, a sharp increase over 1982. Also, in 1983 exports of cattle hides were 61 percent of total commercial slaughter.

The price for hide and offal stands at $6 per hundredweight. That produces some $60 from a 1,000-pound steer. The average price of prime steers on the auction block last week was $62 per hundredweight. The price of the hide would be roughly 10 percent of what a rancher would receive.

Imports of leather and leather products continue to hold a large share of the U.S. market. They increased about 12 percent in 1983, to an estimated $5.1 billion from $4.5 billion in 1982. On balance, in 1983, leather and leather products imports exceeded exports by about $4.7 billion.

International trade in semiprocessed wet-blue chrome cattlehide leather has increased sharply since 1980 because of lower shipping costs and quality advantages. In the wet-blue process, the hair is taken off and chromium is added. This reduces the weight of the pelt for shipping and the chromium makes the hide take on the blue coloring. The hides are placed on a pallet and wrapped with plastic. Then, they are sent to the tanner who will continue the preservation process. Last year, wet-blue exports in the period of January-July increased 22 percent overall.

Essentially what is happening is that we are sending our hides to foreign competitors to process the hides into leather. Then, we are having to purchase the tanned product and finished leather goods at a premium price. With the cost of processing in the U.S. at such a high price, the leather is usually made into products elsewhere in the foreign market and then we repurchase the goods. In essence, we are helping eliminate ourselves from the marketplace. We may want to ask ourselves if the number of U.S. jobs being lost to foreign competition is worth the cost. Each step from hide to finished product is a loss in the value-added process to U.S. workers.

Supply of hides is not a problem for domestic commercial tanneries. The number of cattlehides derived from total commercial slaughter increased an estimated 1 percent to 36.3 million in 1983 from 35.8 million in 1982.

The outlook for the remainder of 1984 indicates, although slaughter will increase slightly, domestic production of leather products will decline. Cattlehide exports will increase, but a strong U.S. dollar will continue to restrict growth in leather exports. Prices of leather imports will continue to be very competitive because of the strong dollar and subsidized raw material costs in several major leather-producing developing countries. Imports continue to capture a larger share of the domestic market than in 1983.

One segment hard-hit by foreign competition and imports is the domestic nonrubber footwear industry. Imports of non-rubber footwear have surged dramatically in the last five years from 404.6 to 581.7 million pairs, increasing import market share from 50.9 percent to 63.6 percent. In 1984 imports have thus far captured 69 percent of the U.S. market. Domestic production has steadily declined. 1984 production to date is down a further 6 percent. Employment throughout the industry has steadily decreased during the period from 148,900 to 132,800 in the direct manufacturing industry alone. Unemployment within the industry is up dramatically from 8.2 percent to 18.7 percent. In a nutshell, imports are up dramatically, but domestic production, employment and worker earnings are down.

Now is the time to determine a means of solving many of these problems. Congress must take measures now if important domestic manufacturing industries and the employment they bring to our workers throughout the nation are to survive.

The answer may be the use of radiation to treat green hides. We may be able to do it domestically without environmental problems. Curing and preserving hides through irradiation could mean salvation for many American workers and revival for some facets of American manufacturing.

The physical layout required to irradiate large quantities of hides must be carefully engineered with appropriate safety considerations but, overall, can be readily envisioned. Hides directly from the fleshing operation could be passed under a gamma radiation source on a continuous belt at a speed which permits sterilization. The irradiation will require close control to achieve the desired results. If the irradiation is too low, complete bacterial kill will not be achieved and the hides will not be preserved. If irradiation is too strong, physical damage to the hide results and subsequent leather made from these hides would be physically weakened. The amount of radiation which is reported to achieve preservation without physical damage is on the order of 3 to 5 Mrads.

If the economics are favorable, the major obstacle that will have to be overcome to introduce irradiation preservation as an alternative to salt curing is the conditions under which hides are currently marketed. Current practice allows hides to be tied in single bundles which are handled, stored and transported as single pieces without being containerized. They are stable in this condition and after brine curing weigh less than the original raw hide. Irradiated hides and skins on the other hand will have to be individually bagged and placed in air-tight containers for transportation and storage. Actual freight rates will be 15 to 20 percent higher based on hide weight. Part of this increased cost might be offset by reclassification of containerized hides as more acceptable materials for transportation than brine-cured hides.

An advantage to using irradiation over the traditional methods is three-fold. The salt used in the process contributes to the weight of the hide which in turn inflates the cost of transportation. The salt causes an increased amount of degradation to the hide. And, getting the salt out of the hide is a problem that irradiation would eliminate. The bottom line is that irradiation does not damage the cologen in the hide while being transported to the tanner. And it eliminates the costly and environmentally hazardous process of salt disposal.

A centrally located irradiator serving a given market area could significantlly reduce the transportation cost. For instance, Oklahoma is in the heart of cattle country in the Southwest and provides an excellent setting for such an effort. With over 2.5 million head of cattle being marketed each year in the state, in which many are sold to neighboring states, Oklahoma is the center of the Southwest cattle industry. But problems in the cattle industry have not been localized; they are nationwide, along with the other problems in agriculture. Use of an irradiator to promote a balance of trade in our favor could ease the blows that many of our cattlemen have taken over the past few years.

Others who will benefit from the construction of an irradiator include the Department of Defense. This will reduce the cost of disposal of defense nuclear waste. But, of course the one who will really benefit from it all will be the consumer. Since my district has a large number of rural people living on the edge of poverty, I can appreciate what irradiation of green hides could mean in the area of new jobs and rural development. This could open new doors of employment for these people. And, for metropolitan areas irradiation could mean the difference between closing the doors of a major manufacturing and processing industry or expansion.

Research on the irradiation preservation of hides and skins using gamma radiation from radioisotopic sources has been largely published by scientists from Eastern Europe and Russia. The published accounts of this research suggest that irradiation preservation of hides and skins is possible.

As mentioned earlier, federal research of irradiation has been concentrated in DOE and USDA. DOE, through its defense nuclear waste program, has taken the lead in promoting commercialization of cesium-137 irradiators. Congress has authorized DOE to construct four demonstration irradiators -- one for sludge treatment in the west; one for pork treatment; one devoted basically to citrus crops in Florida, and a portable unit.

There is no irradiator or specific studies being done on other horticultural or agronomical crops, or the treatment of hides. I am firmly convinced that another demonstration irradiator will greatly enhance commercialization of this process for these commodities.

I am encouraged by the fact that the Congress has passed and the President signed the Energy and Water Development appropriations bill which funded a joint Department of Energy-Department of Agriculture design study for an additional commercial-size irradiator for fruits, vegetables and hides. We are hopeful that the results of that study will be extremely positive towards opening new doors to profitability to farmers and stockmen as well as bringing potential for new jobs for Americans and savings on food processing and thusly costs for consumers.

If the study results are as I think they will be, I will more than likely be back before you next spring asking for authority to build a hide and produce irradiator based on the study.

This is our chance to get a balance of trade in this area of competition. The big question is, do we want to continue weighing the scales in their favor or is it time that we balance the scales of trade.

Mrs. LLOYD. Thank you very much, Wes. If you did not close with that quotation, I was going to use it because I just recently copied it out of your testimony.

So thank you, and we'll be looking forward to your support as we move forward trying to perfect this legislation.

Mr. WATKINS. Thank you. And I want to commend you for your leadership, and the members of the committee and the staff who I know put in a lot of long hours. I hope that they will carefully look at this. It is, as I mentioned, an answer to some of our trade problems, our job problems, and I commend it. If I can be of assistance in any way to you or the staff I hope that you will not hesitate to call on me.

Mrs. LLOYD. Well, we certainly will be working together. I know you've been very active in this concept for a long time. In about 30 seconds, how would this translate to benefits to the farmers of your community? What degree of magnitude?

Mr. WATKINS. One of the biggest problems in the heartland right now, we can produce; but it's the market. We have got to be able to——

Mrs. LLOYD. To what degree will it enhance your market?

Mr. **Watkins**. It would probably enhance it by 50 percent, I think.

Mrs. **Lloyd**. That's tremendous.

Mr. **Watkins**. It would be tremendous.

Mrs. **Lloyd**. Thank you. Thank you very much, Wes.

We are happy now to welcome another one of our colleagues.

I would at this time like to ask for a brief recess because I think there will be some charts that will have to be put up at this time to sort of rearrange our structure. I'm sure this will not last over a couple of minutes; so, with the indulgence of the audience, we will stand in recess for about 2 minutes so you can prepare your charts and we'll not be disrupted. Is that agreeable to you? It won't take over a couple of minutes, will it?

Fine.

[Short recess taken.]

Mrs. **Lloyd**. Now, if everybody has all their props, their visual aids in order, then I think we're ready to start. If anybody's not quite ready, just let me know, but I think we are.

It is certainly equally my pleasure to have my distinguished colleague from the State of Washington here, my friend and my buddy, Congressman Sid Morrison. Sid has worked so closely with us on so many nuclear issues that we are very indebted to him for all of his contributions. He is the chief sponsor of 5605, and I'm also a cosponsor of this legislation. I think this is the bill that will further promote the irradiation of food.

Good morning, and we are anxious to hear what you have to say. Please proceed as you wish, Sid.

STATEMENT OF HON. SID MORRISON, A U.S. REPRESENTATIVE FROM THE STATE OF WASHINGTON

Mr. **Morrison**. Thank you very much, Madam Chairman. You're right; I almost feel like I'm a member of this subcommittee. I wish that I——

Mrs. **Lloyd**. I know that you really feel like you should be sitting over here, and we wish you were, too, believe me.

Mr. **Morrison**. As I entered the room—and I'm going to skip through much of my testimony, Madam Chairman, with the exception of the last several pages which relate specifically to the interests and concerns of this subcommittee—but as I entered the room, I have to admit you have gathered the experts that I have come to know in the last year or so as I have worked on this particular issue. Again, I thank you for your leadership in calling for this particular hearing at this time.

I really am excited about the treatment of food with ionizing energy. We've heard from several, including your own comments, this morning as to the potential applications, and I personally believe it could be revolutionary and the most important development in food preservation since canning and freezing and some other items which showed up about a century ago.

We also have just gone through the concern over materials such as ethylene dibromide, and on the original bill we introduced we had about 50 cosponsors; many of them came on when all of a sudden they realized we were losing some of the options that we had. In our initial hearing in the Agriculture Committee our good mutual friend, Kika de la Garza, launched into a pitch about America suffering from microchemophobia, which I thought was an interesting combination of terms. It points out, really, that many of the materials that we've used through the years are no more dangerous than they were 40 or 50 years ago when they were first studied, but that our ability to detect them——

Mrs. LLOYD. It also sounds like a good phrase for my good friend, Kika de la Garza.

Mr. MORRISON [continuing]. That our ability to detect many of these materials has expanded to the point that some of them, like ethylene dibromide, will come under a great deal of pressure.

Wes Watkins included in his comments some of the potential uses for food irradiation. I will not add to that, although we've found some rather exciting things. I am pleased that in the props that you will have here today you will find some products from various parts of the United States that have been irradiated, treated as part of a research program. Again, until the Food and Drug Administration regulations are finally approved, these are strictly experimental and people should be aware that they should utilize them strictly as volunteers.

But we are pleased—one of the items that I ran over to look at were some cherries that were just brought from my own area. We've done cherry research for the last couple of years in conjunction with the Battelle Memorial Institute, found that not only in addition to being able to control insects and to preserve that product, that they also last 3 weeks longer. So we're finding some rather interesting side effects which are highly beneficial since fresh cherries are a very highly perishable commodity.

Wes Watkins also mentioned the growing international consensus and support for food irradiation around the world. One of the reasons is, as you pointed out in your comment back to him, that many of the other nations of the world do not have all the alternatives that we have and they desperately need to expand the usability of their food sources. Twenty-eight nations, as was mentioned, are now using irradiation at 10 times the level—or, at least, have approved it—at 10 times the level being proposed by the Food and Drug Administration. That's not being critical of our own FDA; we're just saying that they are, as usual, being very conservative in fulfilling their role in protecting the American public until we're absolutely certain about this.

I have also recently started my service on the new Select Committee on Hunger, and feel strongly that we can take our current production of agricultural products and stretch it much farther in reaching our helping hand around to other parts of the world.

I would also like to emphasize that this is not a new technology. This subcommittee is very much aware of up to more than 40 years of research that has gone on. In fact, food irradiation has been studied in more detail than any other food preservation technique over the last four decades and, very simply, it is ionizing energy which penetrates through food killing organisms and microorganisms. While I don't understand all the procedures involved, I do know that we have learned to utilize other energy forms—the light in this room, the heat, radio, television, microwaves, which Congressman Harkin mentioned, ultraviolet light, a number of other energy sources which we've learned to utilize and turned them into servants. I see ionizing energy in exactly the same light, and here's a unique opportunity, now, to make it work for all mankind.

The important thing to remember is that the food absorbs only the energy of the radioactive source and not the radioactivity itself. We don't expect to come out of the dentist's office, having an x ray, with our teeth radioactive because we know it doesn't happen; nor does the table in the doctor's office Become radioactive after being exposed to hundreds of thousands of x rays. It just doesn't happen. Food treated in this way is exactly the same way; in fact, it's physically impossible to induce radiation through the food irradiation process at those levels now being considered.

I personally view food irradiation as a food safety issue. It doesn't leave a residue, which is one of our problems with chemical treatments now. It retards spoilage, kills undesirable biological elements, and I think we will find as we look in greater detail at this that it truly is a consumer and food safety issue.

We were delighted late last month to have the American Medical Association in convention after consideration by several of their committees, endorse our particular bill and the food irradiation process.

The bill, which has been mentioned very kindly by a number of members—and I appreciate your cosponsorship now; I think we're up to 34-some cosponsors—is an effort to build on the proposed Food and Drug Administration regulations which we have in front of that agency now. It does several things, but particularly expands on those regulations. By the way, the comment period for those regulations is now closed; about 4,000 comments were received, and it proposes the 100 kilorads or less, basically, for fresh fruits or vegetables. And I commend Margaret Heckler and all of the people within the Health and Human Services team for their involvement in advancing these regulations.

I think we do need the bill, however, to build upon those proposed regulations. We have the support of a number of groups, and it's been a learning experience for me to consult with a variety of the agencies that have an interest in this subject area, including the Food and Drug Administration, in preparing this legislation.

Basically, the bill retains the definitions that were in the original measure, and that is that food irradiation is not an additive but is, in fact, a process. However, we make sure that it's a process that continues to be well within the authority of the Food and Drug Administration for its analysis and approval.

The bill also provides for ongoing research and development of food irradiation and uniformity, and some other things that I think will be of interest to this committee.

I will discuss in greater detail later the leasing provisions, which are also of interest to this committee.

The most important part of the bill probably is the establishment of a Joint Operating Commission. Again, our attempt is not to add to the bureaucracy, but to provide for this Commission a forum to coordinate largely existing activities that facilitate consumer understanding of this technology.

By the way, within that Joint Operating Commission, which is under the umbrella of the U.S. Department of Agriculture, we certainly include the Department of Energy, Health and Human Services, Environmental Protection Agency, Agency for International Development, the Department of Commerce, and an appointed representative of the public to sit in and be part of the coordinating effort.

Most important to me, though, is the finding that I hear that the public in general has an emotional, almost fearful response to food irradiation. It is our hope that with this bill, particularly the Joint Operating Commission, that we'll promote an open discussion and advance public understanding of this process so that we can eliminate their concerns. I believe very strongly that we'll never obtain large-scale commercial acceptance and application until we have consumer acceptance of the products involved.

I'd like now to spend just a couple of minutes in greater detail on the items that I think are of greatest interest to this particular subcommittee.

I strongly believe that the Federal Government must play an active role in two areas of particular interest to you. The first is expanded Federal research and development into food irradiation, and the second is the leasing of nuclear byproduct source material to the private sector.

The importance of federally sponsored food irradiation R&D cannot be overstated. The many years of food irradiation research, largely conducted by the U.S. Army and the Department of Energy, is now paying dividends. Only because of our prior research efforts can food irradiation be advanced today as a safe and effective substitute to pesticides, as a tool for export expansion, and as a partial answer to world hunger. The experience with this technology proves that Federal research and development pays.

In order to gain widespread commercial application, a food irradiation technical infrastructure needs to be built. More field testing of the technology is required. Different types of radiation sources need to be thoroughly studied including nuclear byproducts like cobalt-60 and cesium-137, the x ray, and machine-generated sources of radiation such as electron beams. Various food commodities need to be studied to see how food irradiation could be used effectively and in a cost-competitive way. Different radiation doses under special conditions also need to be researched to determine the most desirable combination of circumstances and appropriate economies of scale.

My legislation calls for additional Federal R&D for irradiation which is consolidated within the Joint Operating Commission, as I have mentioned. The bill directs that additional research should be conducted, if possible, at agricultural research stations, land-grant colleges and universities, and by national laboratories. This type of coordinated research and development effort, I believe, will help build the technical experience and infrastructure required for widespread commercialization of the food irradiation technology.

I urge this subcommittee and the staff to review this legislation to discern if the R&D efforts envisioned by the bill are adequate and appropriate. Because of your background in research and development activities, I invite you to suggest ways in which my legislation's handling of food irradiation R&D can be improved.

The second issue of special concern for this subcommittee is nuclear byproducts. Currently, cobalt-60 is the predominant source material used for food irradiation. It is unlikely, however, that cobalt alone can handle an expanding irradiation market; in fact, the current cobalt supplies are already controlled by the Canadian Government on an allocation basis. Because of limited supplies, this Nation needs to develop the other major source of gamma radiation—cesium-137.

The Federal Government already owns vast quantities of cesium capsules; there are almost 80 million curies at the Hanford Nuclear Reservation waiting to be used. Additional amounts of cesium can easily be obtained as byproducts of nuclear waste. While there are a few relatively minor problems with the current encapsulation of cesium and the NRC approval of transportation casks, I believe that cesium must be utilized as a source material to fulfill our growing demands for irradiation.

To help facilitate use of cesium, my legislation in section VI establishes guidelines for the leasing of cesium and other nuclear byproducts to the private sector. A fair market price would be charged for the cesium with all revenues returned to the U.S. Treasury. I envision this type of leasing approach, where the Federal Government retains title, as a profitmaking venture which will save the taxpayers of America millions of dollars.

This concludes my testimony Madam Chairman. I welcome this opportunity to testify and I appreciate the special interest of this Subcommittee.

[The prepared statement of Mr. Morrison follows:]

TESTIMONY OF HON. SID MORRISON, A REPRESENTATIVE FROM THE STATE OF WASHINGTON

Good morning, Madam Chairman and Members of the Subcommittee. It's nice to appear once again before this panel as a witness. I've been here so many times before that I almost feel like I'm a Member of this Subcommittee. And if I were a Member, I would be proud because this Subcommittee has exercised wise and farsighted leadership in the promotion of research and development programs, particularly in the nuclear energy field. Our children and our grandchildren will be the beneficiaries of the good work accomplished by this panel.

Today, I'm here not to talk about the breeder reactor or fusion energy and the importance of these technologies to our energy future; instead I'm here this morning to talk about another futuristic and exciting technology which holds similar promise for the agricultural and food processing industry: the treatment of food with ionizing energy.

The impact of food irradiation as a postharvest treatment could be revolutionary; it could be the most important development in food preservation since the introduction of canning and freezing last century. The possibilities are unlimited and exciting. Food irradiation can protect food from pests much like ethylene dibromide (EDB) does. But unlike EDB, it will not leave a residue on the food. If other postharvest fumigants are restricted by EPA, food irradiation is viewed by many as one of the most effective and safe substitutes.

Besides acting as a possible substitute for EDB and other fumigants, low doses of irradiation eliminate trichinosis in pork and would allow consumers to enjoy pork cooked as little as they like and could enhance the export prospects for pork. Use of irradiation stops the medfly in citrus fruits and the codling moth in apples. Irradiation could also destroy botulinum and salmonella in red meats, poultry, and fish and extend the shelf life of fresh fruits, vegetables and grains.

There is a growing international consensus behind food irradiation. Two international organizations, the Joint FAO/IAEA/WHO Expert Committee and the Codex Alimentarius Commission, have recommended the use of irradiation on food up to doses ten times higher than FDA is now proposing. Twenty-eight countries have approved various uses of gamma radiation on at least 40 different foods. Since about a quarter of the food supply in the third world is lost to spoilage, food irradiation could also play a major role in helping feed the world.

The food irradiation technology is not new; we have accumulated over forty years of research data. Food irradiation has been studies in more detail than any other food preservation technique over the past four decades. Food irradiation is ionizing energy which penetrates through food killing organisms and microorganisms. As a farmer, I have always marveled at our expanding use of other energy waves such as visual light, radio, TV, microwave, and ultraviolet light. These energy sources have become friends, and servants. Ionizing energy used to irradiate food is similar in many ways.

As with these energy sources I just mentioned, the food absorbs only the energy of the radioactive source, not the source's radioactivity. For instance, an x-ray in the dentist office does not make your teeth radioactive and the x-ray table in the doctor's office does not absorb radioactivity even after thousands of x-rays. In a sense, exposing food to gamma radiation, x-rays, or machine made radiation is similar to exposing it to electric light: such exposure, no matter how long, will never cause the food to generate electricity.

Indeed, it is physically impossible for food irradiation to induce radiation in food at any of the dose levels now being studies. It is true that irradiation may change the food slightly, but these changes are no more significant than the changes that occur from boiling or freezing food. Experts across the world agree that food irradiation is safe and wholesome. It's interesting to note that severely-ill patients in our hospitals and our astronauts in space are sometimes served foods sterilized with gamma ratiation.

I view food irradiation as a food safety issue. It kills undesirable biological elements which contaminate food without seriously eroding the food's nutritional value. It retards spoilage and keeps the food fresh and more natural-tasting. It does not leave a residue on the food like fumigants. In fact, as a testament to the safety and wholesomeness of food irradiation, the esteemed American Medical Association at their national convention last month endorsed the food irradiation process.

In order to foster consumer and commercial acceptance of food irradiation, I recently introduced major new legislation, H.R. 5605. The bill was the subject of a hearing before a House Agriculture Subcommittee on May 9 and the bill has attracted over thirty cosponsors from both parties and all geographic regions. I'm honored that the Chairlady is an original cosponsor.

This bill builds upon legislation I introduced last November (H.R. 4544) and a proposed Food and Drug Administration regulation which was promulgated in February. H.R. 4544, which had nearly 50 cosponsors, merely changes the definition so that it would be defined as a food process—not a food additive—in the Food, Drug and Cosmetic Act.

The comment period for the FDA regulation has expired and the Agency is now digesting the nearly 4,000 comments they received. The regulation permits limited application of food irradiation primarily for fresh fruits and vegetables up to a dose of 100 Kilorads, again a dose which is one-tenth the standard now accepted by most international authorities. This regulation is an excellent first step in gaining commercial and public acceptance of this technology. I commend Secretary Margaret Heckler for her personal leadership in developing the regulation and seeing that it was formally proposed. However, I believe that we need to build upon the regulation and that is why I introduced my food irradiation bill.

The new bill, Madam Chairman, is entitled the "The Federal Food Irradiation Development and Control Act of 1984". I view this second generation bill as an attempt to find the judicious balance to facilitate acceptance of food irradiation and to accommodate as many interest as possible.

The bill has the endorsement of several major national organizations including the American Medical Association, the National Food Processors Association, the Grocery Manufacturers Association, the National Pork Producers Council, the Association of Seafood Importers, and the United Fruit and Vegetable Association. I have consulted with various federal agencies, including FDA, USDA, DOE, the Department of Commerce, and the White House Office of Science and Technology Policy in developing this legislation.

The bill retains the proposed definition of irradiation of food as a process or treatment and expressly excludes irradiation from the food additive definition. However, FDA would still retain authority to regulate food irradiation for consumer protection in much the same way as they do now. The bill also provides for on-going research and development of food irradiation, national uniformity of food irradiation regulations, and further provides explicit authority for leasing of federally-owned irradiation source materials to the private sector to ensure an adequate supply while ensuring federal safety and transportation standards.

The centerpiece of the bill is the establishment of a Joint Operating Commission to facilitate acceptance of food irradiation. The Commission will operate within USDA and would coordinate and management currently fragmented research and information exchange efforts. It will also act as a liaison to promote consumer acceptance of food irradiation and private development. My intent with the Commission is to do nothing more than provide a forum to coordinate largely existing activities and to facilitate consumer understanding of this technology.

My experience has been that the public in general has an emotional, almost fearful response, to food irradiation. I hope that this bill, particularly the Joint Operating Commission, will promote open discussion of food irradiation so that public concerns about the pending use of irradiation can be addressed.

No matter how successful and safe food irradiation proves to be, it will never obtain large scale commercial application unless there is consumer acceptance. The consumer needs reassurance from the Federal Government and I view the Joint Operating Commission as the least restrictive way to facilitate public acceptance. The last thing we all want is for government to get in the way of the progress in development of commercial food irradiation that we all see coming.

However, I strongly believe that the federal government must play an active role in two areas of particular interest to the Subcommittee. The first is expanded federal research and development into food irradiation and the second is the leasing of nuclear byproduct source material to the private sector.

The importance of federally sponsored food irradiation R&D cannot be overstated. The many years of food irradiation research, largely conducted by the U.S. Army and the Department of Energy, is now paying dividends. Only because of our prior research efforts can food irradiation be advanced today as a safe and effective substitute to pesticides, as a tool for export expansion, and as a partial answer to world hunger. The experience with this technology proves that federal research and development pays.

In order to gain widespread commercial application, a food irradiation technical intrastructure needs to be built. More field testing of the technology is required. Different types of radiation sources need to be thoroughly studied including nuclear byproducts like cobalt-60 and Cesium-137, the x-ray, and machine generated sources of radiation such as electron beams. Various food commodities need to be studied to see how food irradiation could be used effectively and in a cost-competitive way. Different radiation doses under special conditions also need to be researched to determine the most desirable combination of circumstances and appropriate economies of scale.

My legislation calls for additional federal R&D for irradiation which is consolidated within the Joint Operating Commission and the Department of Agriculture. The bill directs that additional research should be conducted, if possible, at agricultural research stations, land-grant colleges and universities, and by national laboratories. This type of coordinated research and development effort, I believe, will help build the technical experience and intrastructure required for widespread commercialization of the food irradiation technology. However, I urge this Subcommittee and the staff to review this legislation to discern if the R&D efforts envisioned by the bill are adequate and appropriate. Because of your background in research and development activities, I invite you to suggest ways in which my legislation's handling of food irradiation R&D can be improved.

The second issue of special concern for this Subcommittee is nuclear byproducts. Currently, cobalt-60 is the predominate source material used for food irradiation. It is unlikely, however, that cobalt alone can handle and expanding irradiation market; in fact, the current colbalt supplies are already controlled by the Canadian government on an allocation basis. Because of limited supplies, this nation needs to develop the other major source of gamma radiation—cesium-137.

The federal government already owns vast quantities of cesium capsules; there are almost 80 million curies at the Hanford Nuclear Reservation waiting to be used. Additional amounts of cesium can easily be obtained as byproducts of nuclear waste. While there are a few relatively minor problems with the current encapsulation of cesium and the NRC approval of transportation casks, I believe that cesium must be utilized as a source material to fulfill our growing demands for irradiation.

To help facilitate the use of cesium, my legislation in section six establishes guidelines for the leasing of cesium and other nuclear byproducts to the private sector. A fair market price would be charged for the ceisum with all revenues returned to the U.S. Treasury. I envision this type of leasing approach, where the federal government retains title, as a profit-making venture which will save the taxpayers of America millions of dollars.

Mrs. LLOYD. Well, thank you very much, Sid, for your very valuable testimony. You have become quite an authority on this subject of food irradiation. The bill that you initiated certainly is a comprehensive approach and identifies the real obstacles that would hinder the further development and application of this technology.

One of the areas of interest to me is your proposal to provide for the leasing of the federally owned cesium-137 isotopes at a fair market value. What are the advantages of leasing the isotopes as opposed to selling them, which has been the normal procedure?

And the second part of the question, how do you determine the value?

Mr. MORRISON. Those are good questions, and let me take a swing at them.

In most legislation, of course, we give the authority presuming that the details will be worked out——

Mrs. LLOYD. How does it look at the present time?

Mr. MORRISON. Well, first of all, the benefits of leasing—essentially, we just clarify that the Department of Energy would have the authority to lease these materials. They could proceed with selling them, as they have the authority now.

Part of the public concern, and you're very well aware of this, over radioactive materials is the ultimate disposition, the disposal, processing, the handling, and the transportation. It would seem to me that the materials we have, the potential for a return of the investment the taxpayers have made—particularly with cesium, which I am most familiar with in my own district—that by retaining title, leasing the materials to private enterprise for insertion into irradiators, that you alleviate many of those concerns.

The transportation, the handling of the materials, its ultimate disposal would remain with the Department of Energy, those people in whom we have great confidence because of the expertise that they have in these areas.

Fair market value, I trust, is like anything else within our system, that it would be determined by what the competition is like; and certainly cobalt, now, as a source material, is the major competition, and——

Mrs. LLOYD. That's from a Canadian source?

Mr. MORRISON. Canada has the major opportunity there, and there is an established price. Cesium has to be based on an equivalent value, and so it probably would be priced at a lower rate but certainly should be competitive.

Mrs. LLOYD. But what——

Mr. MORRISON. I think it will be a minor part of the total cost of irradiation as the source material has a 30-year life.

Mrs. LLOYD. We're looking at the economic factors of irradiation. Just how much of a factor is the price of the isotope in factoring the cost? Is it production facilities or the cost of the isotope? What's the No. 1 big-ticket item?

Mr. **Morrison**. Well, the big-ticket item basically will be the machinery itself; that is, the facility itself. The capital cost will be the most significant as I would see it. We have experts here who have done the research.

We have been talking about—at least, initially—some of these processing facilities——

Mrs. **Lloyd**. Those are long-term investments, though?

Mr. **Morrison**. Long-term investment if, for instance, cesium—currently, the going price is about 10 cents per curie—the initial cost would be about $300,000, perhaps, for a type of facility that might have a total capital cost of $3 million. So it is not a significant——

Mrs. **Lloyd**. This is not an overriding concern?

Mr. **Morrison**. It's not an overriding concern. And again, that material has to be competitive and cannot be prohibitive if, in fact, we're going to advance this technology.

I would like to see a fine line, a line that says yes, we have these materials available; they should be out there working, doing the good things that food irradiation can provide. But let's also consider the taxpayer and have some concern. I would like to be able to continue and expand the research that's been done, and what better source of funding—even though we do not tie them directly together—what better source of funding than from the actual leasing of material with return to the taxpayers as a result of that, and expanding the technology with the dollars that come back from that source.

Mrs. **Lloyd**. Well, I certainly thank you for your leadership. The bells have rung; we have to approve of yesterday's Congressional Record, so we will stand in recess and return shortly.

[Short recess taken.]

Mrs. **Lloyd**. The subcommittee will come to order. Again, we apologize for our absence which was necessary as we must take time to take care of the routine procedures as well.

We are delighted to have our next witness with us today. He's a very knowledgeable gentleman, Dr. Gilbert, who is Deputy Assistant Secretary for Nuclear Materials of the U.S. Department of Energy. Thank you for being with us, Dr. Gilbert; we have your testimony and you may proceed as you wish.

STATEMENT OF DR. F. CHARLES GILBERT, DEPUTY ASSISTANT SECRETARY FOR NUCLEAR MATERIALS, U.S. DEPARTMENT OF ENERGY

Dr. **Gilbert**. Thank you very much.

Mrs. **Lloyd**. Is that our lunch today? Are we going to be here that long?

Dr. **Gilbert**. These are samples of foods that have just recently been irradiated, over the last few days——

Mrs. **Lloyd**. Thank you for bringing them.

Dr. **Gilbert**. [continuing]. At Battelle Memorial Institute in the State of Washington. They are Washington apples and Washington cherries; I'm not sure where the raisins—the almonds probably came from California. But I'm not pushing them since the FDA final regulation has not been published, but they have been irradiated to a few 10's of kilorads, and——

Mrs. LLOYD. Thank you for bringing them to our hearing today.

Dr. GILBERT. You're welcome.

I would like, with your permission, to submit my full testimony for the record, and what I would propose to do instead of reading it or attempting to go through it totally would be to talk to the vugraphs that I have that encompass the——

Mrs. LLOYD. As for you and for the remaining witnesses, all of your complete testimony will be made a part of the record so that you may summarize or bring out your pertinent issues as you wish.

Dr. GILBERT. Good. Thank you.

I was interested in Mr. Harkin's comment about eating irradiated food because I think it was probably a couple of decades ago that, at the Oakland Army Base as a second lieutenant, I had the opportunity to eat some Army irradiated food at that time, and it also hasn't seemed to have harmed me, that I can tell, and it was good food.

What I would like to do, Madam Chairman and members of the committee, is to describe the program that the Department of Energy has been carrying on for the last few years in the area of food irradiation——

Mrs. LLOYD. Excuse me. I think we're going to have to dim our lights a little bit more. We may have to close the outside door as well, to take advantage of the slide presentation.

Dr. GILBERT. I'm quite happy in the interest that this particular committee has been taking in this particular program because I see it as a very beneficial program for the United States, potentially, in the future in the agricultural area.

We are, at the present time, in this beneficial uses program looking at various applications of nuclear byproducts, only one of which is food irradiation. And if you look at this list over here [indicating] you get a feeling for some of the things that we have been doing. For example, we are developing a one-half kilowatt electric battery, an RTG—radio-thermal generator—which uses Strontium-90, which is a byproduct from the spent fuel rods that we process at Richland. We also have been developing self-powered Tritium lights which have been received very favorably by the Department of Defense and certain States that have remote airfields where it is difficult to provide powered lighting 24 hours a day, 7 days a week.

We also have four irradiators either built or under construction or about to be constructed that you see listed there [indicating], some of which are for sludge; some are for both sludge and food, and some devoted totally to food.

Now, from this point on I'm going to talk only to the food irradiation since that's the topic of this particular committee.

To continue, our activities in this area are covered by three general—have three general aspects. First of all, research; then we want to demonstrate some full-scale facilities, and I'll come back to those; and then we are providing technical support activities in support of some of the commercial activities, but in particular, the U.S. Department of Agriculture, and I'll come back to describe the kinds of things we are doing in conjunction with that Department.

The four irradiators that we have or are proposing for food are listed here [indicating]. The first is one that is already in operation at Sandia. It is a small irradiator, has one megacurie of cesium in it. It can handle about 4 tons per day of materials passing through it. We have used it mainly for sewage solids, but we've also used it for some fruit processing.

We are proposing—in fact, have just let the bid, or accepted the bid—for an agricultural cesium irradiator which will be built in Miami, FL, and that will have the capability to expose up to the 100 kilorad level that has been proposed by the Food and Drug Administration at a rate of about 1,000 cartons per hour of food products. In this case, with the Department of Agriculture, we are looking at grapefruit as an example of what we would process through that facility. We hope to have that facility completed by next year.

We are also looking at a pork irradiator, and there, as was mentioned earlier, the radiation level need not be as high. This one will handle several hundred carcasses——

Mrs. LLOYD. Excuse me, Dr. Gilbert. You have four irradiators at the present time?

Dr. GILBERT. No; we don't have four; we have only one operating. We're building three of them.

Mrs. LLOYD. You are in the process of having four?

Dr. GILBERT. Yes.

Mrs. LLOYD. And each one of them has a separate mission?

Dr. GILBERT. That's correct.

Mrs. LLOYD. Thank you; please proceed.

Dr. GILBERT. For the pork irradiator, we don't have a site selected for that yet. That will handle several hundred pork carcasses per day, and we have been working with Iowa State University on that particular one. It will do the job of eliminating the trichinosis in the pork at that level, and we hope to demonstrate this way that it has a commercial viability.

Now, the last irradiator on that list is a transportable cesium irradiator, and there we have a need to do experimentation. That's a very low rate, two cartons per hour. But the purpose of that irradiator is to take the irradiator to the source of the food; for example, the high rate of spoilage was mentioned earlier. The sooner you stop that spoilage, the longer and the better able you are to preserve that food. And so we hope to evaluate the utilization of this transportable irradiator closer to the source of the food product that's being irradiated.

We are carrying on research with the Department of Agriculture in the following five areas: citrus fruits; dried fruit and tree nuts; fresh pork; shellfish, and then the transportable cesium irradiator will be used for a variety of products.

The citrus irradiation, as I mentioned before, is being done cooperatively with the Department of Agriculture, the Agricultural Research Service, and we are being driven by the September 1 date at which ethylene dibromide will be banned for certain applications. Obviously we won't be able to meet that date, but it is a big milestone that will be driving the whole industry here.

We are doing work with dried fruit and tree nuts, and in this particular instance we're working with the Department of Agriculture again, and Oregon State, the California Almond Board, and the California Prune, Raisin, and Walnut Board. In this case, it replaces not ethylene dibromide but methyl bromide, which is a fumigant. We're not proposing to eliminate the total use of methyl bromide; as I understand it, they fumigate these materials several times, and it's the last fumigation that leaves the residual chemicals in the food. The irradiation would be used only for the last treatment.

And then, as was mentioned earlier, we are planning a pork irradiator and we are carrying out a cooperative effort, again with Department of Agriculture, their Animal Parasitology Institute; and the National Pork Producers Council. And, as I mentioned earlier, Iowa State University.

In the area of shellfish, along the eastern seaboard in particular, there are clams, for example, that grow in highly contaminated beds. These clams that grow in those areas, I understand, are not fit for human consumption. Consequently, they cannot be marketed. The effort here, in conjunction with the University of Lowell in Massachusetts, is to demonstrate the ability of radiation treatment to make those clams edible and, hence, marketable.

Now, the transportable irradiator I mentioned already, and it will be used for a variety of applications.

If we go to the next picture, this is what the transportable irradiator will look like in elevation and plan views [indicating]. The irradiator itself—this is a model of that irradiator. Again, it is not intended for a high throughput like some of these irradiators; this is a low rate. The food is put into this cylindrical drum-shaped section here, in a carton, and then rotated around and exposed to a cesium source, which is located in the rectangular box portion of this irradiator.

Now, we have two irradiators that will be prototypic in the sense that they will be full-scale, and the first one of these is the cesium agricultural commodities irradiator and the second is the fresh pork irradiator. I'd just like to give you an idea of what those would look like when they are completed. This is a drawing of the commodities irradiator.

You can see, along the front, cartons on a conveyor belt which will be carried along, picked up by tongs, carried past two flats pallets of cesium capsules, and thence back on, out of the irradiator. They go in through a maze so that radiation can't leave the structure, and the pallets of cesium are lowered—can be lowered into a pool below the irradiator, below ground, so that if there are repairs that need to be made or maintenance that needs to be carried out in the facility, they can be lowered and shielded in that fashion.

Mrs. LLOYD. Dr. Gilbert, what is the relative size of this transportable irradiator?

Dr. GILBERT. Well, I'd have to judge for myself from the picture, here—the transportable irradiator, or—the transportable one is about 100 feet long, and that's its biggest dimension, and—if I remember right—it is about 16 feet high. From the outside it will look like a regular trailer on the highway.

Mrs. LLOYD. So, 16 feet high—we couldn't exactly carry it down the interstate?

Dr. GILBERT. Well, let me check that number.

Mrs. LLOYD. I was wondering how transportable transportable is.

Dr. **Gilbert**. It is designed to be transportable on the highway. The tractor can take this down the highway just like a truck. And so the idea is to make it so that it can be transported to wherever the need is to do the experiments with the fresh produce.

Mrs. **Lloyd**. OK. Thank you for your clarification.

Dr. **Gilbert**. I'm sorry; I was looking here at an 86-foot wall section and judging that it must be 100 feet long. But it's 13 feet high, and 43 feet long. So I stand corrected.

Mrs. **Lloyd**. Thank you.

Dr. **Gilbert**. The pork irradiator is shown in these two views here [indicating]. In this case, the carcasses would be suspended from an overhead conveyor like most of us have seen in meat handling and meat packing houses. The carcasses would then simply be passed by a panel of cesium-137 sources and out the other side. Again, this source can be lowered into the ground to provide shielding if it is necessary to enter the building for maintenance.

There are some other things that are necessary for this program besides the irradiators, and I've tried to list them here [indicating]. We are working on these items also in our program.

One is, we need a way to transport the cesium sources around the country in a safe, acceptable way, and so we are building a transporter which we call BUSS, which is a heavy, shielded cask which will take about a megacurie of cesium at a time. The container has now been built and it is about to go into testing. We have to test it very rigorously to make sure that it will withstand the potential highway accident conditions that it will have to see, and after it has gone through that, then we will license it for DOE use and we will also ask the NRC to license it for commercial use.

For the cesium capsules themselves, we have been over the years conducting tests on those capsules and we have submitted a capsule design to the NRC and have requested that they evaluate them for licensing. It is also my understanding that several private companies—at least to date, two private companies—have also asked NRC to evaluate irradiation facilities for licensing to use the cesium capsules.

We are initiating a program with the Agency for International Development which relates to the import of foods from the Caribbean region and perhaps other parts of South America and the Far East. It's a Third World-type of endeavor. As was mentioned earlier, this kind of activity would be very beneficial to some of the Third World countries.

We are looking at the future potential supply of isotopes, particularly cesium-137, and I'll come back to that.

We are also undertaking to transfer, as rapidly and as totally as possible, the technologies that we have developed in these areas into the private domain.

And then I'd like to talk a little bit, not at this point, but about the future, the potential future of the DOE program in this area.

The next chart reiterates a little bit of what I have already said so I'm not going to repeat that. I've just pretty much said all of these things already.

If we go on to the next slide, you see that we now have the 77 megacuries that are being stored at Richland, WA, and we think we have about another 38 megacuries that could be extracted from waste that is already in spent fuel at Richland and being processed, and another 100 megacuries available from waste being stored at Savannah River. Now, that's all existing waste, and I'll come back—there's also some more potential future waste—and I'll come back to that.

One of the other things we are doing for the future or plan to do for the future is to look at more efficient and better forms for the cesium sources. The cesium sources are now about 2 inches in diameter and there is a fair amount of self absorption of the gamma rays in the sources and they are certainly not as efficient as they could be. We're also looking at different ways of packaging that might be better in other ways. Now this chart here shows you the current requirements for the cesium 137 that we have. I mentioned we have 77 megacuries. Up until a few months ago, beyond the Department of Energy itself, we didn't have any takers for all of this material essentially. But just recently in the past few months we've had hard requests to purchase this material come into Oak Ridge and we have another, a total listed here of 108 megacuries requirement including the requirements for the Department itself and I understand yesterday we got still another purchase order for another 50 megacuries. We will not of course, sell or lease any of this material until FDA completes its licensing process, so these orders are at the moment being held. But you see we have a shortfall now, a potential shortfall or 30 some megacuries.

If you want to go to the next chart—the 77 megacuries is that which is already separated and packaged and I mentioned the 38 megacuries in Purex wastes in the State of Washington and Savannah River, SC, another 100 megacuries. Then in future wastes from Savannah River, we think that through the year 2000 there might be another 100 megacuries available.

Then I list here the potential megacuries in commercial spent fuel, which is not available to the United States because we are not reprocessing the spent fuel from our commercial reactors. But you can see there are much greater quantities of cesium in the commercial fuel than available from Defense fuel.

Other countries, such as France and the United Kingdom and the Soviet Union, presumably could—although to my knowlege they are not, at the moment, capitalizing on this—could extract large quantities of cesium for similar purposes.

Well, Madam Chairman, I'm quite excited about this program like some of my preceding speakers. I think it has great potential for the United States and so I'd like to leave with that thought.

That concludes my presentation.

[The prepared statement of Mr. Gilbert follows:]

TESTIMONY OF DR. F. CHARLES GILBERT, U.S. DEPARTMENT OF ENERGY

I. INTRODUCTION

Madam Chairman, Members of the Committee, I am pleased to represent the Department of Energy (DOE) in this important hearing on the status of food irradiation technology within the United States. I view with special interest the continuing concern of this Committee in programs seeking to develop peaceful uses of nuclear energy for the benefit of mankind and welcome the opportunity to discuss ongoing DOE efforts in this area.

We are currently conducting programs to assess the beneficial application of selected isotope byproducts that result from defense-related activities. Chart 1 presents a list of activities within the scope of the DOE Byproduct Utilization Program. This Program was initiated several years ago at Sandia National Laboratories as a result of the support of this Committee. Recently, support for the program has come from the House Armed Services Committee as part of their efforts to help develop beneficial, cost-effective applications for the defense nuclear waste generated by DOE Defense Programs. Emphasis is currently being placed on two of the highest activity products, strontium-90 and cesium-137.

One of the strontium-90 initiatives is to design and construct a relatively high-power (500 watts electrical) radioisotope thermoelectric generator for possible use by the military. Tritium radioluminescent airfield lights, utilizing phosphor compounds, are being developed jointly with the Department of Defense and the State of Alaska at our Oak Ridge National Laboratory. These self-powered lights have already been used in highly successful military tactical operations; e.g., Grenada Invasion.

The cesium-137 development applications have been in the field of sludge, food, and commodity gamma irradiation.

The nuclear fuel processed by DOE for our Defense Programs contains several radioactive, thermally hot isotopes after the special nuclear materials have been separated and recovered for use in our national defense. We have found that separation of cesium-137 during the reprocessing of spent fuel assemblies and subsequent waste treatment activities removes more than 90 percent of the gamma radiation load of this "nuclear waste." The resulting cesium-bearing material represents a fraction of the total volume of this "waste." Thus, in 1974, DOE began the separation of cesium-137 from defense waste at Richland, Washington, and, in addition, purified and encapsulated this material for interim storage at the Richland Waste Encapsulation and Storage Facility (WESF). Such separation has simplified interim waste management and reduced the cost of ultimate disposal of the remaining fractions of the "nuclear waste." This approach has also provided a usable inventory of cesium-137 for the Byproducts Utilization Program.

II. CURRENT DOE FOOD IRRADIATION ACTIVITIES

The DOE Byproducts Utilization Program supports current initiatives in food irradiation. The goal of these initiatives is to develop and remove the impediments to commercial beneficial uses of nuclear byproducts. Cesium-137, which decays with emission of gamma radiation, is similar to cobalt-60, a manmade radioactive isotope producing gamma radiation, and can be used effectively as a radiation source for food irradiation treatment.

The focus of food irradiation activities in the Byproducts Utilization Program is on low-dose radiation treatment of foods at levels below 100 krads. This is consistent with the research and development approach of the Atomic Energy Commission (AEC) during the "Atoms for Peace" program of the 1960's. These doses are appropriate for the insect disinfestation of fresh produce and the inactivation of parasites in meat. This focus is somewhat different than the historical AEC low-dose food irradiation activities that stressed the potential extension of the shelf lives of fresh foods through radiation treatment.

CHART 2

Specific activities supported by the DOE regarding food irradiation include research, full-scale facility validation, and technical support efforts.

CHART 3

This chart presents the pertinent information for the various irradiation facilities within the scope of the DOE program.

CHART 4

A. RESEARCH.

Research in food irradiation is being conducted in conjunction with the U.S. Department of Agriculture (USDA) and several universities. The objectives of these research efforts are to define the parameters critical to the irradiation treatment of agricultural commodities. First, the dose must be established that effectively inactivates specific pests so as to bring commodities in compliance with Federal quarantine regulations. Secondly, the effective dose must not adversely affect those commodity properties such as color, odor, taste, etc.

Specific initiatives are:

CHART 5

1. Citrus. The DOE is cooperating with the USDA/Agricultural Research Service in Florida to determine the viability of irradiation treatment of grapefruits as an alternative to ethylene dibromide (EDB) fumigation quarantine treatment. DOE has conducted several small-scale irradiation treatments of Florida grapefruit at the Sandia National Laboratories' cesium irradiation facilities. These small-scale treatments have led to larger scale studies conducted by USDA in various commercial cobalt-60 irradiation facilities and have established a basis for the implementation of this treatment by industry faced with an Environmental Protection Agency ban on the use of EDB as a citrus fumigant after September 1, 1984.

2. Dried Fruit and Tree Nuts. Cooperative efforts are underway with the USDA/Agricultural Research Service; USDA/Economic Research Service; Oregon State University; the California Almond Board; and the

California Prune, Raisin, and Walnut Board to assess the feasibility of treating almonds, raisins, and walnuts with radiation as a partial replacement for fumigation with methyl bromide. These commodities are produced in tremendous quantities (about 26,000 tons/day) in California during the fall and currently must be fumigated several times to destroy feeding insects. Final fumigations applied after the commodities are packaged can leave residues of the chemical greater those acceptable to foreign importers. A final treatment with radiation could potentially accomplish the same disinfestation result with a concurrent reduction in residual chemical fumigant levels. Insect susceptibility to irradiation, product responses, taste panel tests, and economic feasibility studies are being conducted by Oregon State University to assess this potential application of food irradiation technology.

3. Fresh Pork. Efforts with the USDA Animal Parasitology Institute, the National Pork Producers Council (NPPC), and Iowa State University are nearing the site selection and facility design stage regarding the irradiation treatment of fresh pork to inactivate trichina and other parasites which pose a potential health threat to man. Research on the effectiveness of irradiation in inactivating trichina parasites in ground and fresh pork has been very successful and has indicated that rather low doses are required (about 30 krads). These doses are much below those proposed as acceptable by the FDA and have resulted

in no adverse qualities in the pork as evaluated by scientific taste panels. Much of the data gained in this activity supported by the DOE will be used in an NPPC petition to the FDA to include irradiation of fresh pork in their final regulations. An assessment of consumer attitudes regarding food irradiation in general and pork irradiation in particular has been conducted under the direction of NPPC and has indicated important issues (e.g., wholesomeness, effectiveness, etc.) that must be addressed if irradiation treatment of foods is to be accepted by consumers.

An economic feasibility assessment has also been conducted regarding fresh pork irradiation. Studies indicate that, if the technology is implemented by large processors (e.g., 1,000-2,000 carcasses per day), the use of DOE cesium byproduct material shows favorable potential. Costs for irradiation treatment by such large processors are estimated at less than 1 cent per pound.

4. Shellfish. The DOE is supporting the University of Lowell, Massachusetts, in efforts to assess the potential for irradiation treatment of shellfish (clams, oysters) harvested from potentially polluted beds along the eastern coast of the United States.

CHART 5a

Clams from lightly polluted beds are cleansed (depurated) in clean seawater exposed to ultraviolet light where pathogens residing in the tissues as a result of pollution are expelled into the clean seawater and destroyed. This technique is not applicable to clams harvested from moderately or highly contaminated beds. Initial research has shown that shellfish can withstand substantial doses of gamma radiation during depuration; thus, radiation may offer at potential way to harvest clams from highly contaminated beds and safely cleanse them prior to introduction into the human food market.

5. Transportable Cesium Irradiator (TPCI). In order to conduct meaningful research on irradiation treatment of fresh commodities, the effect of complicating variables (such as time since harvest, temperature of storage and shipment, distance and time of shipment, etc.) must be minimized. Further, for research results to be valid, irradiation of the particular pests of concern must be conducted at the appropriate stage in the life cycle of the pests. These factors have dictated the need for a small-scale flexible research irradiation facility that can be transported to sites where infested commodities are harvested or collected for determination of irradiation applicability. The transportable irradiator is such a flatbed-mounted cesium irradiation unit, which is being fabricated by the Foster-Wheeler Corporation.

CHART 6

Operation should commence in 1985. The transportable irradiator will contain approximately 250,000 curies of cesium-137 in four Waste Encapsulation Facility capsules and will be licensed by DOE or the Nuclear Regulatory Commission as appropriate. It will be capable of irradiating unit-size cartons of commodities as part of research initiatives on various products. Use is projected at multiple USDA locations throughout the country, as well as by commercial firms interested in gaining limited basic research data on the feasibility of irradiation treatment of their specific products.

B. FULL-SCALE FACILITY VALIDATION

To accomplish the technology transfer goals of the DOE program, several full-scale facilities are being designed and fabricated.

CHART 7

These facilities will serve as a validation of cesium irradiation technology and will address technical and institutional issues such as licensing, economics, operational reliability, etc., which will influence the potential for commercial implementation of the technology. Two full-scale food irradiation facilities are planned: the cesium agricultural commodities irradiator (CACI) and the fresh pork irradiator.

1. CACI. The cesium agricultural commodities irradiator will be located at the USDA Subtropical Horticultural Research Station in Miami, Florida. The facility will be designed and constructed by DOE. Subsequent operation could be conducted by the USDA.

CHART 8

The commodities irradiator will utilize 3 million curies of cesium-137 in approximately 50 capsules to treat tote loads (6 standard cartons each) or pallets of agricultural commodities. Cesium will be stored in a water pool and raised out during irradiation cycles. Such treatments will simulate potential commercial irradiation conditions and will also provide sufficient quantities of irradiated commodities for assessments of economics of treatment, storage and marketing studies, etc. The commodities irradiator will be licensed by NRC and operated by the USDA. It will also serve as a tool to evaluate feasibility of radiation treatment of commodities from the Caribbean Basin area, which must currently be fumigated with soon-to-be-banned EDB in order to meet United States quarantine restrictions.

The commodities irradiator project will also involve the Agency for International Development (AID) as a cooperating agency. The facility will be used by USDA and AID to train students, faculty, and operators from developing countries of the Caribbean Basin and will be utilized by visiting scientists to conduct research on commodities of regional interest.

2. Fresh Pork Irradiator. This facility is being designed to validate to the pork packing industry the concept of using irradiation treatment to produce trichina-safe fresh pork.

Chart 9

The facility will utilize 2-3 million curies of cesium-137 in Waste Encapsulation Facility capsules and a conveying mechanism for whole or split hog carcasses, which simulates the systems used in packing plants.

It is DOE's intent to site this facility at a university that will be competitively solicited to serve as host for a broad-ranging irradiation research institute, using the irradiator as a foundation. The institute will possess the capability to extensively evaluate the options for irradiation of fresh pork and will conduct assessments of irradiation effectiveness; potential changes, if any, caused in the meat by irradiation involving taste, color, odor, and other properties; the economics of the process; and the need for specialized temperatures or atmospheric environments. Because the institute will be broad based, other potential uses for irradiation treatment involving other foods, as well as nonfoods, can be investigated. The institute, at a university, can involve students in disciplines ranging from biology and food sciences to nuclear engineering in multidisciplinary research activities.

DOE expects to competitively solicit a site for this irradiation institute in late Fiscal Year 1984 and will proceed with design and fabrication activities shortly thereafter.

C. TECHNICAL SUPPORT ACTIVITIES

In addition to food irradiation research and facility validation initiatives being supported by the DOE, several efforts supporting the technology in a broader fashion are being pursued.

CHART 10

1. Beneficial Uses Shipping System (BUSS). The DOE is fabricating a large radioactive shipping container able to carry 1 million curies of cesium-137 in 16 capsules at a time.

CHART 11

This cask will be compatible with the DOE Waste Encapsulation and Storage Facility at Richland and the full-scale irradiators, such as the commodities irradiator and the fresh pork irradiator. The BUSS will enable more economic transportation of large quantities of isotope from the Waste Encapsulation Facility, and it will be licensed by the DOE and the Nuclear Regulatory Commission for potential use in commercial irradiation facilities. The thick-walled BUSS body has been fabricated, and analyses are nearing completion so that licensing activities can commence within the next month.

2. WESF Capsule Evaluation. The Waste Encapsulation Facility capsules available for use as radiation sources have been extensively tested by DOE to insure their integrity under a variety of operating and potential accident conditions. These tests have been documented by DOE in various reports and have been recently summarized in a Pacific Northwest Laboratory report, which has served to expedite our negotiations with the Nuclear Regulatory Commission concerning the acceptability of using these sources in DOE, as well as commercial irradiation, facilities. DOE is currently interacting with the Nuclear Regulatory Commission to determine specific acceptable irradiator designs and conditions for safe use of Waste Encapsulation Facility capsules as radiation sources. Additional tests of the capsules are being conducted to justify use of the sources in irradiators under varying operating conditions.

Under the planned terms of DOE's lease of cesium Waste Encapsulation Facility capsules to industry, DOE will accept responsibility for return of the sources for ultimate disposal once their radioactivity levels have decreased below those justifying beneficial use. Because DOE has an ongoing interest in the performance of these sources over time, capsules from DOE facilities and perhaps commercial facilities may be periodically removed for examination and evaluation of the capsule performance. These evaluations will contribute to the data base regarding capsule performance under diverse conditions and will assist in guiding future DOE byproduct encapsulation activities.

3. Agency for International Development (AID) Cooperation. The status of international food irradiation activities is addressed later in this hearing. However, the DOE has recognized the international interest in the technology and its potentially dramatic applicability to many developing countries of the world. In those countries where refrigeration and transportation systems may be inadequate, radiation may play a significant role in increasing food supplies through the reduction of postharvest losses. Postharvest loss control is a major goal of AID's program in the developing world, and DOE is cooperating extensively with AID to assist in evaluating the potential for this technology in the Caribbean Basin, Central and South America, and Southeast Asia.

CHART 11a

4. Isotope Supply.

The AEC began encapsulating purified cesium chloride at the Waste Encapsulation Facility in 1974 and since that time AEC/ERDA/DOE has produced 1,575 capsules containing a total of 77 million curies of cesium-137.

CHART 12

Chart 12 shows the DOE requirements for 21.24 Mci and the commercial and foreign requirement of 87.25 Mci per the Oak Ridge National Laboratory Sales Office. Full reimbursable cost for new cesium has not yet been determined.

CHART 13

As this chart shows, this supply is a small fraction of the amount of cesium potentially available from all sources over the next 20 years. Most of the isotope, however, is contained in spent fuel rods from commercial power reactors that are currently being stored on-site at these facilities. Within DOE Defense Programs we are investigating options for additional purification and encapsulation of cesium-137 from defense activities at Richland and Savannah River. However, it is apparent that any near-term major demand for radioactive isotopes by the food industry must be met to the extent possible by cobalt-60. Cesium has been and will be a supplementary radioactive isotope supply. Only reprocessing of spent commercial fuel, if economically feasible, could dramatically increase existing or projected inventories of encapsulated cesium-137.

With regard to cobalt-60, the DOE at one time produced cobalt-60 for use by commercial industry. However, upon emergence of commercial suppliers of this isotope, DOE withdrew from further major production of cobalt-60 and currently produces approximately 700,000 curies per year in the Advanced Test Reactor in Idaho. The use of DOE defense production reactors to produce cobalt-60 at Savannah River was investigated recently by DOE. However, current defense commitments at our Savannah River reactors preclude any such use of these facilities until the 1990's.

5. Technology Transfer. The DOE goal of technology transfer intimately involves the private sector. Only with the acceptance by this sector of irradiation as a technically, economically, and socially feasible technology will this goal be met. Recognizing the responsibility to conduct the research necessary to support rapid technology transfer to industry, DOE has competitively solicited private industry to design and fabricate facilities such as the transportable irradiator and commodities irradiator. These solicitations have provided a broad opportunity for industry to become involved in the technology and to develop the expertise necessary to carry the technology forward into the commercial sector. The DOE will continue to involve industry interested in supplying irradiation equipment, as well as those industrial groups interested in using the technology that must, in the final analysis, provide the commercial capability for food irradiation.

6. Future of DOE Food Irradiation Efforts. With the successful use of the transportable irradiator, validation of cesium irradiation technology in the commodities irradiator and fresh pork irradiators, licensed use of the BUSS and acceptance by NRC of the viability of cesium Waste Encapsulation Facility sources, the major current Byproducts Utilization Program efforts in food irradiation will be completed.

Thank you for your interest and cooperation in this program.

BYPRODUCT UTILIZATION PROGRAM

PROGRAM ELEMENT	LEAD CONTRACTOR	CURRENT STATUS
ISOTOPIC POWER Sr-90 500 WATT(e) RTG	TELEDYNE INC/ORNL	PROTOTPYE IN PRODUCTION
SELF-POWERED TRITIUM LIGHTS	ORNL	FAVORABLY ACCEPTABLE TO ARMY, AIR FORCE, FAA, ALASKA AND FLORIDA
FOOD/SLUDGE R&D FACILITIES - Cs-137 SIDSS	SANDIA	IN OPERATION IRRADIATING SLUDGE, FOOD, OTHER COMMODITIES
- Cs-137 TPCI	CH2M-HILL/FOSTER WHEELER	UNDER DESIGN; WILL BE USED BY PNL AND USDA FOR R&D
FOOD IRRADIATION DEMO FACILITIES - Cs-137 CACI	CH2M-HILL/ROCKWELL INTERNATIONAL	UNDER DESIGN; TO BE CONSTRUCTED IN MIAMI, FL, FOR USDA CITRUS R&D
- PORK IRRADIATOR	TBD	RFP FOR SITE SELECTION TO BE ISSUED FY84
ISOTOPE TRANSPORTATION - Cs/Sr BUSS CASK	SANDIA	COMPLETING MANUFACTURE AND BEGINNING SAFETY LICENSING REVIEW
ALBUQUERQUE SLUDGE IRRADIATOR Cs-137	ALBUQUERQUE DOE	ON HOLD, CITY HAS NOT BEEN ABLE TO OBTAIN EPA AND STATE FUNDING

Chart 1

CURRENT DOE FOOD IRRADIATION ACTIVITIES

A. RESEARCH

B. FULL-SCALE FACILITY VALIDATION

C. TECHNICAL SUPPORT ACTIVITIES

Chart 2

DOE IRRADIATORS

IRRADIATOR	DOSE	C_s - 137 LOADING	THROUGHPUT	PURPOSE
SANDIA IRRADIATOR FOR DRY SEWAGE SOLIDS (SIDSS)	1 MRAD	1 MCI	4 TONS/DAY	DEMONSTRATE ACCEPTABLE* ALTERNATE TECHNOLOGY FOR SLUDGE PATHOGEN
COMMODITY AGRICULTURAL CESIUM IRRADIATOR - CITRUS (CACI)	< 100 KRADS	3 MCI	1000 CARTONS/HR	R&D TO REPLACE EYTHYLENE DIBROMIDE (EDB) FUMIGATION OF FRUIT AND VEGETABLES
PORK IRRADIATOR	30 KRADS	2-3 MCI	200-600 CARCASS/DAY	R&D FOR ELIMINATION OF THE THREAT OF TRICHINOSIS IN US PORK BY 1987
TRANSPORTABLE CESIUM IRRADIATOR - TPCI	< 100 KRADS	.25 MCI	2 CARTONS/HR	R&D FOR USE BY USDA TO EVALUATE EFFICACY OF LOW DOSE COMMODITY IRRADIATION NEAR HARVEST VICINITY

* HAS ALSO BEEN USED FOR FOOD, ALGAE, AND OTHER IRRADIATION EXPERIMENTATION

Chart 3

RESEARCH

1. CITRUS
2. DRIED FRUIT AND TREE NUTS
3. FRESH PORK
4. SHELLFISH
5. TRANSPORTABLE CESIUM IRRADIATOR (TPCI)

Chart 4

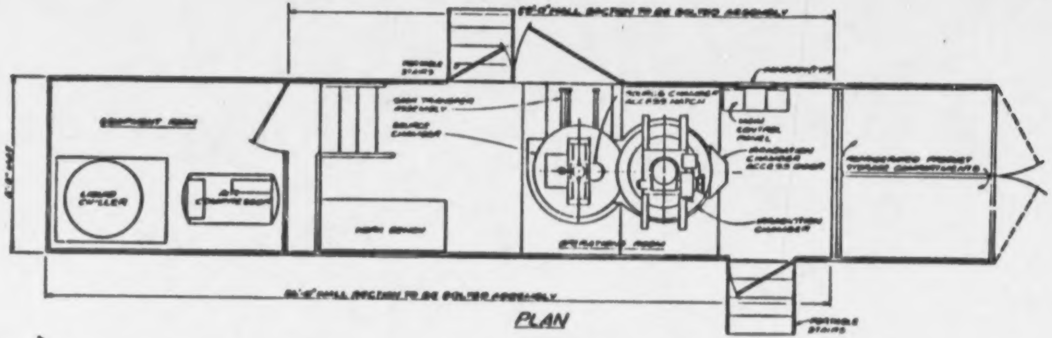
RESEARCH

- CITRUS
  - COOPERATIVE EFFORT WITH USDA/ARS
  - ALTERNATIVE TO EDB REQUIRED BY SEPTEMBER 1, 1984
- DRIED FRUIT AND TREE NUTS
  - COOPERATIVE EFFORT WITH USDA/ARS AND ERC; OREGON STATE UNIVERSITY; CALIFORNIA ALMOND BOARD; CALIFORNIA PRUNE, RAISIN, AND WALNUT BOARD
  - PARTIAL REPLACEMENT FOR FUMIGATION (METHYL BROMIDE)
- FRESH PORK
  - COOPERATIVE EFFORT WITH USDA ANIMAL PARASITOLOGY INSTITUTE; NPPC, IOWA STATE UNIVERSITY
  - TRICHINA FREE PORK

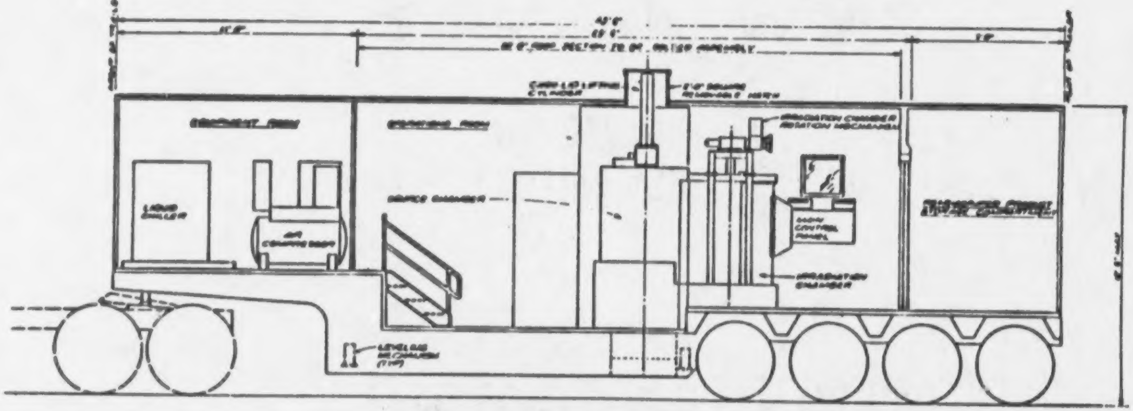
Chart 5

RESEARCH (CONTINUED)

- o SHELLFISH
  - SUPPORTING UNIVERSITY OF LOWELL, MA
  - DESTROY PATHOGENS
- o TRANSPORTABLE IRRADIATOR
  - POTENTIAL USE AT MULTIPLE USDA LOCATIONS
  - IRRADIATE UNIT-SIZE CARTONS
  - DATA OBTAINED AT APPROPRIATE STAGE IN LIFE CYCLE OF PESTS AND COMMODITIES


EQUIPMENT ROOM
LIQUID CHILLER
AIR COMPRESSOR
PORTABLE STAIRS
SOURCE CHAMBER
WORK BENCH
OPERATING ROOM
MAIN CONTROL PANEL
IRRADIATION CHAMBER ACCESS DOOR
IRRADIATION CHAMBER
REFRIGERATED PRODUCT STORAGE COMPARTMENTS

PLAN


42'6"
EQUIPMENT ROOM
LIQUID CHILLER
AIR COMPRESSOR
OPERATING ROOM
SOURCE CHAMBER
IRRADIATION CHAMBER ROTATION MECHANISM
MAIN CONTROL PANEL
IRRADIATION CHAMBER
LEVELING MECHANISM (TYP)

ELEVATION- INTERIOR

TRANSPORTABLE CESIUM IRRADIATOR (TPCI)

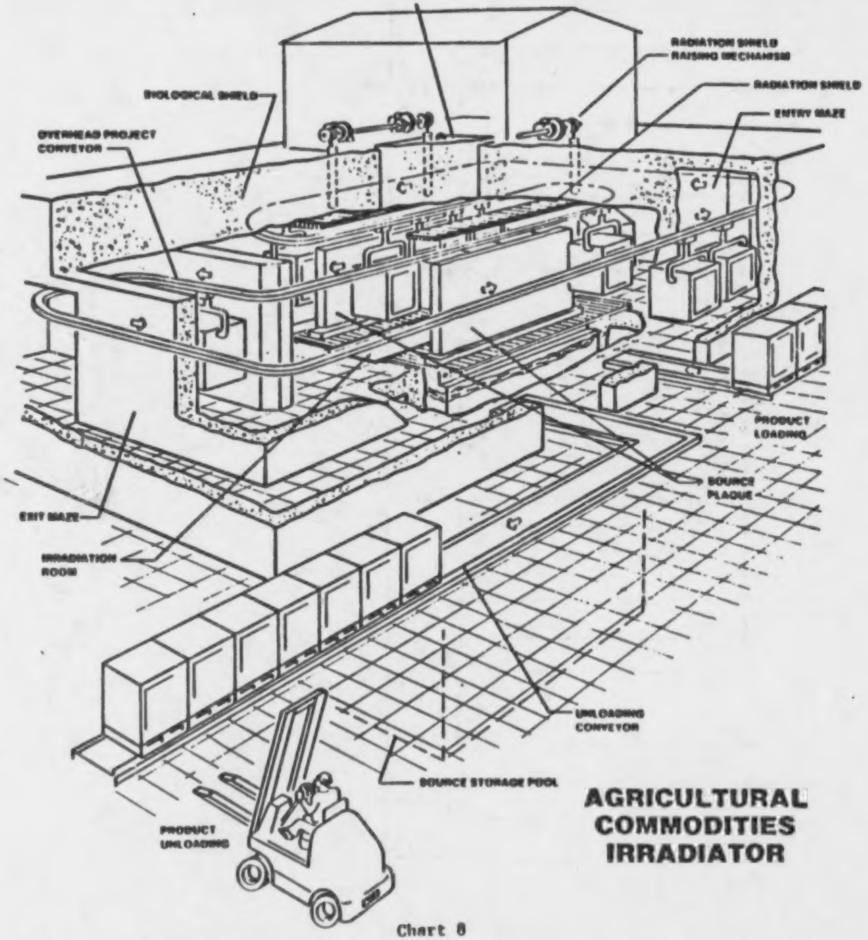
GENERAL LAYOUT - PLAN AND ELEVATION

Chart 6

FULL-SCALE FACILITY VALIDATION

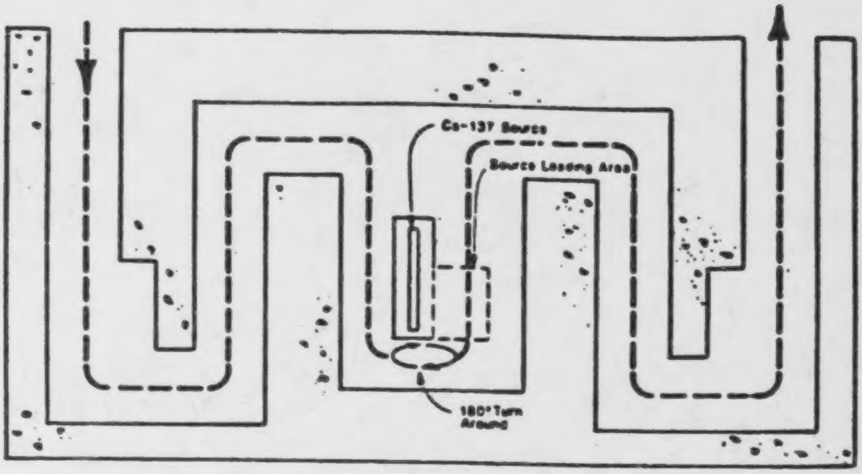
1. CESIUM AGRICULTURAL COMMODITIES IRRADIATOR (CACI)
2. FRESH PORK IRRADIATOR

Chart 7

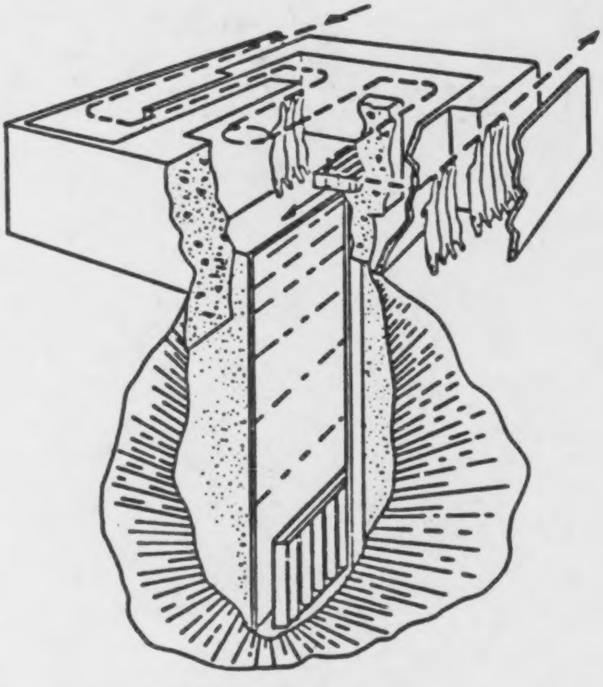

RADIATION SHIELD
RAISING MECHANISM
RADIATION SHIELD
ENTRY MAZE
BIOLOGICAL SHIELD
OVERHEAD PROJECT
CONVEYOR
PRODUCT
LOADING
SOURCE
PLAQUE
EXIT MAZE
IRRADIATION
ROOM
UNLOADING
CONVEYOR
SOURCE STORAGE POOL
PRODUCT
UNLOADING

**AGRICULTURAL
COMMODITIES
IRRADIATOR**

Chart 8


Cs-137 Source
Source Loading Area
180° Turn Around

"Plan View of Pork Irradiator"



"The Cs-137 source is shown in its secure position at the bottom of the storage well. In use, the source is raised to a position between the two conveyor rails (shown by the dashed lines) which carry the hog carcasses."

Chart 9

TECHNICAL SUPPORT ACTIVITIES

1. BENEFICIAL USES SHIPPING SYSTEM (BUSS)

2. CESIUM CAPSULE EVALUATION

3. AGENCY FOR INTERNATIONAL DEVELOPMENT (AID) COOPERATION

4. ISOTOPE SUPPLY

5. TECHNOLOGY TRANSFER

6. FUTURE OF DOE FOOD IRRADIATION EFFORTS

Chart 10

TECHNICAL SUPPORT ACTIVITIES

- o BENEFICIAL USES SHIPPING SYSTEM (BUSS)
  - DESIGNED TO TRANSPORT 1 MCi Cs-137
  - DESIGNED TO TRANSPORT 5 KWth Sr-90
  - DOE AND NRC LICENSED

- o WESF CAPSULE EVALUATION
  - LONG-TERM TESTS TO SUPPORT WET LOAD, DRY STORAGE AND IRRADIATION
  - ADDITIONAL THERMAL CYCLE TEST TO SUPPORT WET LOAD AND STORAGE, AND DRY IRRADIATION

- o AID COOPERATION
  - DOE COOPERATION WITH AID IN CARRIBEAN BASIN, CENTRAL AND SOUTH AMERICA, AND SOUTHEAST ASIA

Chart 11

TECHNICAL SUPPORT ACTIVITIES (CONTINUED)

- o ISOTOPE SUPPLY
  - 77 Mci Cs-137 PRESENTLY ENCAPSULATED
  - 38.7 Mci Cs-137 POTENTIALLY AVAILABLE FROM PUREX WASTE
  - 102 Mci Cs-137 POTENTIALLY AVAILABLE AT SAVANNAH RIVER
- o TECHNOLOGY TRANSFER
  - USE OF PRIVATE INDUSTRY TO DESIGN AND CONSTRUCT DEMONSTRATION FACILITIES
- o FUTURE OF DOE FOOD IRRADIATION EFFORTS
  - COMPLETE DEMONSTRATION FACILITIES
  - INVESTIGATE SAVANNAH RIVER AND RICHLAND OPTIONS FOR PURIFYING AND ENCAPSULATING Cs-137

Chart 11a

CESIUM - 137 REQUIREMENTS

DOE

NUCLEAR ENERGY/GERMANY WASTE MANAGEMENT R&D	3	Mci
ALBUQUERQUE SLUDGE	12	Mci
CACI	3	Mci
PORK	2	Mci
TPCI	0.25	Mci
ANNUAL SALES (E.G. MEDICAL THERAPY)	1	Mci
SUBTOTAL	21.25	Mci

OTHER REQUIREMENTS

RADIATION STERILIZERS	40	Mci
IOTECH	12	Mci
RADIATION TECHNOLOGIES	15	Mci
CEA (FRENCH)	0.25	Mci
AECL (CANADA)	20	Mci
TOTAL	108.50	Mci
AVAILABLE	77	Mci
SHORTFALL	31.5	Mci

Chart 12

ESTIMATED INVENTORIES OF CESIUM-137 FROM VARIOUS SOURCES

SOURCE		EFFECTIVE INVENTORY DATE	MILLION CURIES
HANFORD	- CESIUM CHLORIDE CAPSULES THROUGH 6/84 (1575 CAPSULES)	1/83	77
	- FUTURE PUREX WASTES	1/91	38.7
SAVANNAH RIVER PLANT	- CURRENT WASTES	1/83	102
	- FUTURE WASTES	1/2001	109
COMMERCIAL SPENT FUEL	- ACCUMULATED THROUGH 1981	1/83	520
	- ACCUMULATION THROUGH 2020	1/2021	11,000

Chart 13

Mrs. LLOYD. Well, thank you very much. I think you timed it right; we're going to have some votes in just a few minutes, again.

What is the DOE's perception of the marketplace? How does it compete in marketing cesium as an alternative to cobalt?

Dr. GILBERT. Well, all I can say to that is that we seem to have firm orders for the cesium that we have, and therefore my impression is that it will be very marketable, particularly because at the present time the cobalt supply, as I have heard, is being limited because of Canada's limited production. We do produce about a million curies of cobalt in our ATR reactor——

Mrs. LLOYD. How many?

Dr. GILBERT. About a million curies in our ATR reactor at Idaho, but I think the Canadians are probably producing at least 10 times that much in their reactors.

Mrs. LLOYD. Would not the marketplace then drive up the cost of cesium if there is a shortfall of the cobalt?

Dr. GILBERT. At the present time the cesium is based on the DOE pricing policy, which we call full cost recovery so it is not related to the market value. However, prior to leasing this material—and if the bill referred to earlier is passed—then we would go to the fair market value.

Mrs. LLOYD. Does DOE prefer leasing to selling the isotopes, the cesium isotopes?

Dr. GILBERT. Yes. We have considered the concept of leasing to be desirable from the overall standpoint of the country in the following sense, that if we lease the material and eventually we will get that defense waste back and can dispose of it as we do the rest of our defense waste—if it were sold to a private company, we foresee that they would have difficulties.

Mrs. LLOYD. What would our liabilities be in such a leasing arrangement? What is the Federal Government's liability in leasing?

Dr. GILBERT. I can't answer that. I'm afraid I'm not——

Mrs. LLOYD. Well, thank you. You have done a beautiful job and we certainly appreciate it, Dr. Gilbert. We look forward to a long working relationship with you as we proceed with this very valuable and very exciting concept. Thank you very much.

Dr. GILBERT. Thank you.

Mrs. LLOYD. And now we welcome our first panel of witnesses which includes Richard Cunningham, Director of Fuel Cycle and Material Safety for the U. S. Nuclear Regulatory Commission; we have Dr. Terry Kinney, who is the Administrator of the USDA Research Service; and Dr. Sanford Miller, who is Director of the Bureau of Foods at the Food and Drug Administration of the Department of Health and Human Services.

We welcome you, gentlemen. I am trying to decide whether this is a notice quorum or a recorded quorum—it's a notice? OK, since this is to notice, then we'll proceed until some more bells ring. I hope they don t ring anytime soon.

Again, we have your complete testimony so you may proceed as you wish. Mr. Cunningham, I believe you're the lead man today.

STATEMENT OF RICHARD E. CUNNINGHAM, DIRECTOR, DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, U.S. NUCLEAR REGULATORY COMMISSION

Mr. CUNNINGHAM. Thank you very much, Madam Chairman.

My name is Richard Cunningham; I am Director of the Nuclear Regulatory Commission's Division of Fuel Cycle and Material Safety. As was the case with preceding witnesses, Madam Chairman, I do have a statement that I would like to include in its entirety. I will perhaps read some of it, but not all of it.

Mrs. LLOYD. It is received without objection.

Mr. CUNNINGHAM. I am pleased for this opportunity to provide testimony on the NRC's regulation of commercial irradiators.

The NRC's regulatory authority stems from the Atomic Energy Act of 1954, as amended, and the Energy——

Mrs. LLOYD. Mr. Cunningham, if you could get your microphone just a little bit closer, we could hear you better. Thank you.

Mr. CUNNINGHAM. The NRC's regulatory authority stems from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. These acts cover the use of byproducts, source, and special nuclear material. The NRC's fundamental mandate for the use of these materials under the acts is to provide adequate protection of the public health and safety and to prevent an unreasonable risk to the common defense and security.

Section 274 of the Atomic Energy Act of 1954 permits the NRC to enter into agreements with the States whereby the NRC relinquishes and the States assume regulatory authority over most uses of byproducts, source, and special nuclear materials within the States. This means that agreement States would regulate byproduct material irradiators located within the States except those that are operated by a Federal Government agency. There are presently 27 agreement States. The NRC maintains a continuing relationship with each agreement State to assure compatibility of the State's regulatory program and its adequacy to protect the public health and safety.

The use of radioisotopes, for example, cobalt-60 or cesium-137, irradiators is governed by NRC's rules which address basic licensing and radiation safety requirements for the protection of both radiation workers and members of the public. They do not address the quality of the products subject to irradiation except to assure that the products remain free of radioactive contamination. The matter of product quality does not fall within the NRC mandate; for example, in the case of irradiators used for sterilization of medical products, NRC does not determine that the irradiated products will achieve the proper degree of sterility. Also, the NRC does not assure the availability of radioisotopes used in irradiators.

Radioisotopes have been used for commercial irradiation for two or three decades. There are now 35 commercial irradiators licensed by the NRC and the agreement States. All of the irradiators currently use cobalt-60 as the irradiation source.

The basic radiation safety considerations are the same for licenses issued by either the NRC or an agreement State. In the evaluation of an application for a commercial irradiator, matters such as source integrity, design of the irradiator safety systems, training and experience of personnel, and the radiation safety program for operation of the irradiator are considered. With proper design and operating procedures, commercial irradiators can be operated safely without significant radiation risk to workers or the public. Radiation safety operating experience has been good thus far, although two major radiation exposures have occurred. In one case, a worker received a serious exposure when, as a major contributing factor, he failed to follow the operating procedures before entering the irradiator cell. In another case, a worker performing maintenance received a serious radiation exposure as a result of bypassing safety systems in violation of licensed operating procedures. The NRC regulations were subsequently amended to require automatic systems designed to ensure that a worker cannot enter the irradiation cell when the radioactive sources are unshielded.

Turning to the question of food irradiation, as has been noted by preceding witnesses, experimental irradiation of food has been carried out in this country for a number of years. Adequate radiation protection standards and licensing requirements exist to prevent contamination of foodstuffs and provide radiation protection for workers.

In summary, Madam Chairman, the NRC involvement with commercial irradiators is limited to radiation protection. Both the NRC and agreement States have the regulatory structure in place for licensing these devices and have the technical staffs capable of conducting the safety evaluations. We are not involved with the quality of irradiated products, the technical or economic feasibility of product irradiation, or assuring a source of radioisotope supply. These matters are outside the scope of radiation safety. Since our regulations for irradiators are established and operating experience under the regulations has been good, the NRC is not conducting, nor do we presently foresee a need to conduct, safety-related research to enhance the regulatory base. We look to the private sector or other Government agencies to conduct any research needed to demonstrate that new design concepts or equipment components meet present requirements for radiation safety.

Madam Chairman, that completes my formal part of the testimony. I will be happy to answer any questions you might have.

[The prepared statement of Mr. Cunningham follows:]

TESTIMONY OF
RICHARD E. CUNNINGHAM
DIRECTOR, DIVISION OF FUEL CYCLE AND MATERIAL SAFETY
U. S. NUCLEAR REGULATORY COMMISSION

BEFORE THE
SUBCOMMITTEE ON ENERGY RESEARCH AND PRODUCTION
COMMITTEE ON SCIENCE AND TECHNOLOGY
UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING
REGULATION OF COMMERCIAL IRRADIATORS

MY NAME IS RICHARD CUNNINGHAM. I AM THE DIRECTOR OF THE NUCLEAR REGULATORY COMMISSION'S DIVISION OF FUEL CYCLE AND MATERIAL SAFETY. I AM PLEASED FOR THIS OPPORTUNITY TO PROVIDE TESTIMONY BEFORE THE SUBCOMMITTEE ON ENERGY RESEARCH AND PRODUCTION ON THE NUCLEAR REGULATORY COMMISSION'S (NRC) REGULATION OF COMMERCIAL IRRADIATORS.

THE NRC'S REGULATORY AUTHORITY STEMS FROM THE ATOMIC ENERGY ACT OF 1954, AS AMENDED, AND THE ENERGY REORGANIZATION ACT OF 1974, AS AMENDED. THESE ACTS COVER THE USE OF BYPRODUCT MATERIAL (RADIOISOTOPES), SOURCE MATERIAL (NATURAL URANIUM OR THORIUM), AND SPECIAL NUCLEAR MATERIAL (FISSIONABLE MATERIAL). THE NRC'S FUNDAMENTAL MANDATE FOR THE USE OF THESE MATERIALS UNDER THE ACTS IS TO PROVIDE ADEQUATE PROTECTION OF THE PUBLIC HEALTH AND SAFETY AND TO PREVENT AN UNREASONABLE RISK TO THE COMMON DEFENSE AND SECURITY.

SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED, PERMITS THE NRC TO ENTER INTO AGREEMENTS WITH STATES (AGREEMENT STATES) WHEREBY THE NRC RELINQUISHES AND THE STATES ASSUME REGULATORY AUTHORITY OVER MOST USES OF BYPRODUCT MATERIAL, SOURCE MATERIAL, AND SMALL QUANTITIES OF SPECIAL NUCLEAR MATERIAL WITHIN THE STATES. THIS MEANS THAT AGREEMENT STATES WOULD REGULATE BYPRODUCT MATERIAL IRRADIATORS LOCATED WITHIN THE STATES EXCEPT THOSE THAT ARE OWNED AND OPERATED BY A FEDERAL GOVERNMENT AGENCY. THERE ARE PRESENTLY 27 AGREEMENT STATES. EACH AGREEMENT PROVIDES THAT THE STATE WILL USE ITS BEST EFFORT TO MAINTAIN COMPATIBILITY

WITH THE NRC'S PROGRAM. THE NRC MAINTAINS A CONTINUING RELATIONSHIP WITH EACH AGREEMENT STATE TO ASSURE COMPATIBILITY OF THE STATE'S REGULATORY PROGRAM AND ITS ADEQUACY TO PROTECT PUBLIC HEALTH AND SAFETY.

THE USE OF RADIOISOTOPES, E.G., COBALT 60 OR CESIUM 137, IN IRRADIATORS IS GOVERNED BY NRC RULES MAINLY CONTAINED IN 10 CFR PART 20, STANDARDS FOR PROTECTION AGAINST RADIATION, AND 10 CFR PART 30, RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL. THESE REGULATIONS ADDRESS BASIC LICENSING AND RADIATION SAFETY REQUIREMENTS FOR PROTECTION OF BOTH RADIATION WORKERS AND MEMBERS OF THE PUBLIC. THEY DO NOT ADDRESS THE QUALITY OF THE PRODUCTS SUBJECT TO IRRADIATION EXCEPT TO ASSURE THAT PRODUCTS REMAIN FREE OF RADIOACTIVE CONTAMINATION. THE MATTER OF PRODUCT QUALITY DOES NOT FALL WITHIN THE NRC MANDATE. FOR EXAMPLE, IN THE CASE OF IRRADIATORS USED FOR STERILIZATION OF MEDICAL PRODUCTS, THE NRC DOES NOT DETERMINE THAT THE IRRADIATED PRODUCTS WILL ACHIEVE THE PROPER DEGREE OF STERILITY. ALSO, THE NRC DOES NOT ASSURE THE AVAILABILITY OF RADIOISOTOPES USED IN IRRADIATORS.

RADIOISOTOPES HAVE BEEN USED FOR COMMERCIAL IRRADIATION FOR ABOUT 20 YEARS. THERE ARE NOW 35 COMMERCIAL IRRADIATORS LICENSED BY THE NRC AND THE AGREEMENT STATES. ALL OF THE IRRADIATORS CURRENTLY USE COBALT 60 AS THE IRRADIATION SOURCE. THE AMOUNT OF RADIOACTIVE MATERIAL IN THESE IRRADIATORS RANGES UP TO 10,000,000 CURIES. THE MAIN COMMODITY BEING IRRADIATED TODAY IS MEDICAL

PRODUCTS SUCH AS GLOVES, SYRINGES AND SUTURES. OTHER COMMERCIAL PRODUCTS, SUCH AS PLASTIC IMPREGNATED WOOD, ARE ALSO IRRADIATED.

THE BASIC RADIATION SAFETY CONSIDERATIONS ARE THE SAME FOR LICENSES ISSUED BY EITHER THE NRC OR AN AGREEMENT STATE. IN THE EVALUATION OF AN APPLICATION FOR A COMMERCIAL IRRADIATOR, MATTERS SUCH AS SOURCE INTEGRITY, DESIGN OF THE IRRADIATOR SAFETY SYSTEMS, TRAINING AND EXPERIENCE OF PERSONNEL, AND THE RADIATION SAFETY PROGRAM FOR OPERATION OF THE IRRADIATOR ARE CONSIDERED. WITH PROPER DESIGN AND OPERATING PROCEDURES, COMMERCIAL IRRADIATORS CAN BE OPERATED SAFELY WITHOUT SIGNIFICANT RADIATION RISK TO WORKERS OR THE PUBLIC. RADIATION SAFETY OPERATING EXPERIENCE HAS BEEN GOOD THUS FAR, ALTHOUGH TWO MAJOR RADIATION EXPOSURES HAVE OCCURRED. IN ONE CASE, A WORKER RECEIVED A SERIOUS EXPOSURE WHEN, AS THE MAJOR CONTRIBUTING FACTOR, HE FAILED TO FOLLOW THE OPERATING PROCEDURES BEFORE ENTERING THE IRRADIATOR CELL. IN ANOTHER CASE, A WORKER PERFORMING MAINTENANCE RECEIVED A SERIOUS RADIATION EXPOSURE AS A RESULT OF BYPASSING SAFETY SYSTEMS IN VIOLATION OF LICENSED OPERATING PROCEDURES. THE NRC REGULATIONS WERE SUBSEQUENTLY AMENDED TO REQUIRE AUTOMATIC SYSTEMS DESIGNED TO ENSURE THAT A WORKER CANNOT ENTER THE IRRADIATION CELL WHEN THE RADIOACTIVE SOURCES ARE UNSHIELDED.

TURNING TO THE QUESTION OF FOOD IRRADIATION, IT IS NOTED THAT EXPERIMENTAL IRRADIATION OF FOOD HAS BEEN CARRIED OUT BY BOTH THE PRIVATE SECTOR AND GOVERNMENT AGENCIES FOR A NUMBER OF

YEARS. ADEQUATE RADIATION PROTECTION STANDARDS AND LICENSING REQUIREMENTS EXIST TO PREVENT CONTAMINATION OF FOODSTUFFS AND PROVIDE RADIATION PROTECTION FOR WORKERS. IN ANY PARTICULAR CASE, HOWEVER, LICENSING MUST BE BASED ON SOUND DESIGN AND OPERATING PROCEDURES TO ASSURE ADEQUATE RADIATION PROTECTION. IT MUST ALSO BE COUPLED WITH APPROPRIATE CHECKS AND BALANCES TO MITIGATE THE RADIOLOGICAL CONSEQUENCES OF MALFUNCTIONS OR ACCIDENTS SHOULD THEY OCCUR.

IN SUMMARY, THE NRC INVOLVEMENT WITH COMMERCIAL IRRADIATORS IS LIMITED TO RADIATION PROTECTION. BOTH THE NRC AND AGREEMENT STATES HAVE THE REGULATORY STRUCTURE IN PLACE FOR LICENSING THESE DEVICES AND HAVE THE TECHNICAL STAFFS CAPABLE OF CONDUCTING THE SAFETY EVALUATIONS. WE ARE NOT INVOLVED WITH THE QUALITY OF IRRADIATED PRODUCTS, THE TECHNICAL OR ECONOMIC FEASIBILITY OF PRODUCT IRRADIATION, OR ASSURING A SOURCE OF RADIOISOTOPE SUPPLY. THESE MATTERS ARE OUTSIDE THE SCOPE OF RADIATION SAFETY. SINCE OUR REGULATIONS FOR IRRADIATORS ARE ESTABLISHED AND OPERATING EXPERIENCE UNDER THE REGULATIONS HAS BEEN GOOD, THE NRC IS NOT CONDUCTING, NOR DO WE PRESENTLY FORESEE A NEED TO CONDUCT, SAFETY RELATED RESEARCH TO ENHANCE THE REGULATORY BASE. WE LOOK TO THE PRIVATE SECTOR OR OTHER GOVERNMENT AGENCIES TO CONDUCT ANY RESEARCH NEEDED TO DEMONSTRATE THAT NEW DESIGN CONCEPTS OR EQUIPMENT COMPONENTS MEET PRESENT REQUIREMENTS FOR RADIATION SAFETY.

THIS COMPLETES MY PREPARED TESTIMONY. I WILL BE PLEASED TO ANSWER QUESTIONS WHICH THE SUBCOMMITTEE MIGHT HAVE.

Mrs. **Lloyd**. Well, thank you very much, Mr. Cunningham.

Dr. Miller, we welcome your testimony at this time.

STATEMENT OF DR. SANFORD A. MILLER, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. CLYDE TAKEGUCHI, DIVISION OF FOOD AND COLOR ADDITIVES, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. **Miller**. Thank you, Madam Chairperson.

Again, with my colleagues, I appreciate your invitation to include my full statement in the record and I will just try to summarize some of my remarks.

Mrs. **Lloyd**. Please proceed as you wish.

Dr. **Miller**. Before I begin, I would like to introduce my colleague, Dr. Clyde Takeguchi of the Food and Color Additives Division in the Center for Food Safety and Applied Nutrition, who has been principally responsible for monitoring our food irradiation activities. Dr. Takeguchi is also available for questions if required.

While the use of irradiation for preserving food was explored as early as 1936, food irradiation research in the United States started in earnest in the late 1940's. And rather than bore you with another discussion of the long history of food irradiation, let it suffice to say that as a result of what was at that time a widespread interest in food irradiation, it wasn't surprising that FDA played an important role in cooperation and collaboration with other institutions, both in Government and the private sector, in suggesting wholesomeness testing and measurement procedures for these products.

The fundamental health concerns for foods treated with ionizing radiation have not changed substantially for 40 years. First, there was the possibility of induced radioactivity; second, there were concerns for the possible long-term toxicological effects of the radiolytic products formed in foods as a consequence of irradiation; and third, there was concern about the effects of irradiation on the microbial flora of the food, as well as on the nutritional quality of the treated food. As a result, the research designed to test wholesomeness and quality was directed primarily toward the resolution of these questions. In particular, the two concerns associated with the safety of irradiated foods that received the most attention were the possibility of induced radioactivity in food, and the possible exposure of the public to new chemicals, sometimes called radiolytic byproducts, formed as a result of the irradiation process.

As a result of the focus on these two areas there has developed over the past 40 years a body of scientific data which we believe sufficient for the evaluation of the food irradiation. Indeed, for the first issue—that is, the induction of radioactivity in food components—substantial data was collected by the National Bureau of Standards and the National Academy of Sciences as early as the 1960's to enable them to conclude that an increase in radioactivity could not be detected in food if the radiation sources were restricted to cobalt-60, cesium-137, or machines that produce radiation at appropriate energy levels. Thus, the concern that consumers will be exposed to radiation is unfounded since induced radioactivity simply cannot occur under the conditions proposed for food irradiation. Although previous witnesses have emphasized this point, I think it important that we at the FDA also emphasize that we agree with that statement.

The second issue, the safety of radiolytic products, has required a longer and much more complex evaluation. In the beginning, attempts were made to assess these products for safety by using traditional animal feeding studies. However, many difficulties were encountered in development of appropriate criteria for such studies. It is simply difficult to study food, as compared to food additives or food contaminants, in this traditional way.

By the late 1970's it was clear that a reevaluation of the criteria based on traditional animal studies for determining the safety of irradiated foods was necessary if rational evaluation and regulation was to take place. In the fall of 1979 I, as the newly appointed Director of the then-Bureau of Foods, which is now called the Center for Food Safety and Applied Nutrition—and again, maybe something else next month—I established the Bureau of Foods Irradiated Food Committee. This committee was charged to review the Agency's practice for evaluation of the safety of irradiated foods and to recommend criteria for safety evaluation according to the then—current state-of-the-art knowledge in toxicology, nutrition, and radiation chemistry. By that time, increased understanding of the radiation chemistry of the potential residues associated with food irradiation allowed us to develop and apply new, appropriate criteria to evaluate the safety of foods irradiated under different conditions.

With this in mind, the committee reported to me in 1980 that further safety testing of foods irradiated below 1 kGy, that's 100 kilorads, and minor ingredients such as spices irradiated at doses up to 50 kGy, would serve no useful purpose. The committee also concluded that the type and amount of radiolytic products in foods irradiated below 1 kGy was such that the irradiated food was as safe as the unirradiated food. Furthermore, there was no significant difference in nutritional value under these conditions.

With your permission, Madam Chairperson, I'd like to submit a copy of that report for the record.

Mrs. LLOYD. Please do. I think that would be a very valuable report.

Dr. MILLER. Thank you.

[Material to be supplied follows:]

RECOMMENDATIONS FOR EVALUATING THE SAFETY OF IRRADIATED FOODS

FINAL REPORT

JULY 1980

MEMBERSHIP OF THE IRRADIATED FOOD COMMITTEE

Chairman

Dr. Lawrence R. Valcovic
Division of Toxicology

Executive Secretary

Dr. Clyde A. Takeguchi
Division of Food and Color Additives

Members

Dr. Anthony P. Brunetti
Division of Chemistry and Physics

Dr. Victor Frattali
Division of Nutrition

Mr. William B. Greear
Division of Toxicology

Dr. David G. Hattan
Division of Toxicology

Prepared for the Director, Bureau of Foods, FDA

The intended technical effects from exposure of food to ionizing radiation include: sprout inhibition, insect control, and the different food preservation modes which involve various levels of microbial destruction. These applications extend from low doses for limited shelf-life extension to high doses for complete sterilization of foods (Figure 1). It is noteworthy that existing alternative methods for achieving these effects in foods require the use of a variety of chemical and physical means. The versatility of irradiation can be seen from the variety of applications. Irradiation may be used as a substitute for food additives (nitrite), fumigants (ethylene dibromide, ethylene oxide), plant regulators (maleic hydrazide), and as a food processing technique for food preservation (canning, pasteurization).

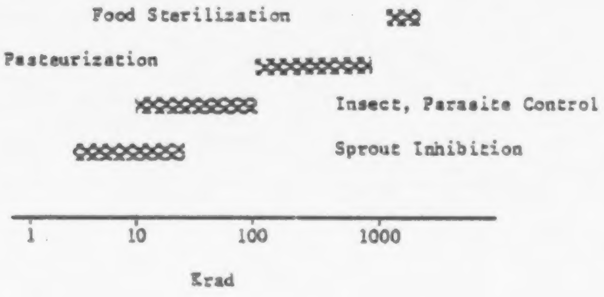


Figure 1 - Categories of intended use for food irradiation.

INTRODUCTION AND BACKGROUND

The Irradiated Foods Committee was authorized on September 10, 1979 and established on October 23, 1979 to provide a total reassessment of all relevant issues applicable to irradiated foods. Since that time the Committee has become acquainted with the subject and accompanying problems by reviewing the relevant literature, interviewing appropriate FDA personnel and international experts knowledgeable in the area of radiation chemistry and toxicological evaluation (see Appendix I).

The Committee was charged with the following tasks:

1. To review current policy.
2. To examine the foundation and soundness of that policy and its past implementation, and
3. To establish those toxicologic requirements appropriate for assessing the safety of irradiated food consistent with the level of human exposure, where the degree of testing is consistent with the potential risk as predicated on the level of human exposure. These requirements would be analogous to, and consistent with, the philosophy supporting the Cyclic Review of direct additives.

The Committee emphasizes that this report is a policy recommendation and not a petition, petition guideline, FEDERAL REGISTER (FR) document, or a comprehensive review of all data submitted to FDA and all available scientific literature. We forsee the development of guidelines for petitioners and a FR document as tasks of future committees.

Because of these differing applications, questions have arisen regarding which provisions of the Federal Food, Drug, and Cosmetic Act are relevant to irradiated foods. Regardless, of whether one considers the source of radiation as an unsafe "food additive," or whether the food is adulterated because of exposure to radiation, or whether irradiation is viewed as a process, the safety requirements for irradiated foods remain the same.

Microbiological concerns for the safety of irradidated foods are substantially the same as those for other methods of food preservation as expressed in the Bureau's 1967 Staff Seminar Report: Radiation Application to Food[1] and Joint FAO/IAEA/WHO Expert Committee Report: Wholesomeness of Irradiated Food[2]. For example, the traditional heat processing of canned foods to provide a sterile, shelf-stable food is based on a specific thermal kill criterion for Clostridium botulinum spores. This criterion requires that the heat processing reduce the original spore count by twelve log units ("12D process"). The parallel process utilizing radiation sterilization of foods (radappertization) is evaluated by the same standard of efficacy as the conventional thermal processes. The 12-D dose varies with the particular food irradiated; for pork, beef, and chicken this dose has been found to range from 2.4 to 4.5 Mrads and defines, in each case, the "sterile dose."

From a number of studies on the radiation stability of vitamins, proteins, fats and other nutrients, it is known that several nutrients are sensitive to degradation by ionizing radiation (see also Appendix II) . This sensitivity, however, depends not only upon the nature and composition of the food system, but also on a number of controllable factors such as the dose, characteristics of the radiation used, temperature of the product being irradiated, and the relative presence or absence of oxygen in the product environment during irradiation. Hence, the destruction of labile nutrients can be minimized by careful selection of the conditions for irradiation. Some of the macronutrient components - amino acids such as cystine, methionine and tryptophan, for example - are more sensitive to irradiation than others. The amounts that are destroyed, however, are usually insignificant compared to the unirradiated food or to a product treated by a conventional process. Criteria for the safety evaluation of the nutritional adequacy of irradiated foods, are essentially identical with those expressed in the 1967 report. When irradiation results in the significant loss of important micronutrients, enrichment may be considered appropriate.

For past safety evaluation, toxicological indices and protocols were applied to irradiated foods as if the whole irradiated food was a discrete chemical entity similar to a "conventional" food additive. It was recognized that there were problems associated with such studies. The most significant of these problems was to achieve dietary concentrations of the food additive in the animal tests which would be multifold exaggerations of concentrations to which humans would be exposed. Many foods constitute a significant percentage of the human diet (see Appendix III) and significant exaggeration of these cannot be obtained without disturbing the nutritional balance of the laboratory test animal. Solutions to these problems were not readily available with the state-of-the-art in toxicology and in the chemistry of irradiated foods at that time. Significant progress had been made in both of these areas in the ensuing years as will be discussed.

Toxicology is an applied and integrative science and it's progress relies on the development of new information in the basic sciences, improvements in test protocol design and execution, as well as on the continually growing volume of information on the toxicology of a variety of chemical classes. Our understanding of the molecular changes underlying many gross toxic effects has increased immensely since 1967.

Because of the increased public awareness of potential harm from the growing number of chemicals in the human environment, there has been an impetus towards the development of new and improved toxicological tests. The area that has received the greatest attention over the past ten years has been the development of short-term tests for detecting chemicals with mutagenic activity. The initial reason for the development in this area stemmed from the concern that chemicals would cause mutations that would be deleterious and thereby increase the burden of inherited diseases in future generations. More recently, the high costs (both money and time) involved in obtaining data from mammalian bioassays have motivated the development of more rapid methods for detecting chemical carcinogens. The empirical demonstration of a high correlation between mutagenicity and carcinogenicity is a sufficient basis for establishing a role for mutagenicity testing as a predictive tool for carcinogenicity. That there is evidence for a mutational component in some types of cancer (retinoblastoma, malignant melanoma, etc.) lends additional credibility to the predictive use of such tests.

Much has been written on the current status of the various toxicological tests and strategies of their employment. Because of the general awareness of this progress within the scientific community an additional comprehensive review of the state-of-the-art in toxicology was considered unnecessary by the Committee. Certainly, it has been necessary for the Committee to become aware of the current procedures. In this context, we consulted with Bureau staff who are involved in the Sensitivity of Method (SOM) and Cyclic Review documents, as well as examined the toxicological tests currently being used by the International Project in the Field of Food Irradiation.

RADIATION CHEMISTRY

As a basis for further discussion and to clearly outline the reasons for reliance on the results of chemical analyses of radiolytic products as an important factor in safety evaluation, key features of food irradiation chemistry will be reviewed. This review will briefly consider the significance of each characteristic of radiation as it defines or limits the changes brought about in food or food components. More detailed discussions of these issues are available in the scientific literature[3].

Ionizing radiation is, in comparative terms, high energy. Radiation quanta in this part of the electromagnetic spectrum are measured in millions of electron volts. The energy source for irradiating foods may be a decaying radioactive nuclide or a machine-generated electron beam at energy levels below 10 MeV. Since a photon energy of 10 MeV is near the minimum level required to induce radionuclides, there is no significant radioactivity above that due to naturally ocurring isotopes induced in irradiated food[4]. Both radiation sources result in essentially the same scheme of chemical events in irradiated food. Of particular interest is the absolute amount of energy absorbed by food. This absorbed energy is the quantity which establishes the net potential for molecular alteration, regardless of how energetic the source emissions are.

Total absorbed energy is expressed as radiation dose, typically in rads or grays. A rad is defined as 100 ergs/gram or 10^{-2} joules/kg. The new international unit of radiation dose is the gray (Gy) which equals 100 rad. (The more familiar unit "rad" is used in this report.)

It should be emphasized that the total energy absorbed is small for even the largest anticipated doses (sterilization of red meat). For example, if all the energy absorbed in a one megarad (1 Mrad) dose were converted to heat energy the sample temperature would rise only 2.4°C per unit weight, assuming the food sample had the heat capacity of water (1 cal/°C). This is about 3.3 percent of the energy needed to raise the temperature of water from room temperature to its boiling point. On a unit weight basis then, these radiation energies are much less than those absorbed in cooking.

Ionizing radiation results in the formation of free radicals, which are characteristically unstable and very reactive chemical intermediates. Free radicals in food are initiated either directly by interaction with high energy electrons, or indirectly, primarily by reaction with hydroxide radicals and low energy solvated electrons. These latter two species result from the radiolysis of water and are the primary radical initiating agents responsible for the formation of most of the subsequent radiolysis products. Consequently, the amount of water in a given food and the extent of hydration of various food molecules has a profound influence on the quantitative and qualitative aspects of the radiolysis yield.

Most free radicals are short-lived intermediates; their intrinsic reactivity ensures that they will normally react within fractions of a second after their formation to form more stable molecules. Free radicals with half-lives of minutes are not uncommon particularly at low temperatures and in environments which limit their diffusion. Free radicals are not entirely indiscriminate in selecting a reaction pathway to an end product. The actual mechanistic pathway is influenced by conventional chemical factors such as concentrations of possible reactants, the relative rate constants for competing reactions, and the mobility of the radicals. As a result, these parameters confer considerable mechanistic selectivity to a given radical and serve to constrain and therefore limit the types of resultant, stable radiolytic products (RPs) formed.

RADIOLYSIS PRODUCTS IN FOOD

The chemistry of foods, isolated food components, and various model food systems exposed to ionizing radiation has been extensively investigated, especially in an attempt to identify the RPs formed. Foods, both irradiated and unirradiated, are chemically complex and may contain hundreds of discrete chemical species. Since many of these compounds are present in the low ppm (or ppb) range, the complete chemical characterization of food is technically not feasible. Hence, while the radiolysis data available in the scientific literature are insufficient to completely catalog the identity and quantity of each RP formed in any particular irradiated food, this body of data circumscribes the type and amount of radiation chemistry which is likely to occur in foods. The estimation of the following two factors are of prime importance in proceeding with a rationale for the safety evaluation of irradiated foods.

A. The probable total yield of RPs in food as a function of absorbed radiation dose, and

B. Some assessment of the fraction of these RPs which are unique radiolytic products (URPs) to the irradiated food.

TOTAL RADIOLYTIC PRODUCTS

The quantitative yield of RPs in food is primarily a function of the magnitude of the absorbed radiation dose. However, secondary factors such as food temperature, composition, viscosity, and environment are recognized as important to the quantity and type of RPs formed. These latter parameters can often be controlled and optimized to provide the most desirable product.

The amount of radiation absorbed remains the first criterion however, in determining the amount of radiation chemistry which occurs. Results from the Army's high dose program on high protein meats, as well as those from numerous model systems, show that radiolysis yields may be characterized as generally increasing linearly with absorbed dose. In addition, based on the energetics of ion pair production, the yield of new species formed (equivalent to RPs) can be calculated from the following expression:[5]

$$\text{Yield (in mmol/kg)} = \text{Dose (krad)} \times G \times 10^{-3}$$

where G is the number of molecules formed or destroyed per 100 eV absorbed.

It has been shown that G-values determined from the irradiation of individual compounds in solution, or from the irradiation of simple mixture (model systems), can be used to predict the total G-value in the actual food matrix[6].

The utility of G-values for estimating yields in irradiated foods is enhanced by the discovery that individual food components tend to produce the same radiolysis products when isolated, or when occuring as natural components of complex foods[7]. Army research workers at the Natick

Laboratory have found that, qualitatively, the RPs formed from the lipid fractions of beef, chicken, and pork are largely similar. The quantities of these RPs are dependent only on the proportion of fat in the irradiated meat. Expected cross-over RPs are thus minimal; for example, the reaction between lipid-derived and protein-derived free radicals are found to be limited by reactions occurring across interfacial regions between tissue phases in meat. This apparent "compartmentalization" of food components considerably restricts the spectrum of possible RPs likely to occur within or across classes of foods. Thus, foods of similar chemical composition, irradiated under similar conditions, will contain RPs derived from common precursors and such irradiated foods may reasonably be viewed in a generic sense.

For purposes of estimating the total levels of RPs in food, a value of $G_T=1$ has been selected. The results noted above, as well as those from the Natick Laboratory,[7] suggest that if food irradiation practices result in an organoleptically acceptable product, the actual G_T will be adequately characterized by this value. In practice, with various foods and conditions, this factor may at times be greater or less than one, but current information supports unity as a reasonable policy-making assumption. Variations of G_T of plus or minus 100% should not significantly alter the arguments based on an assumed value of G=1. Therefore, as indicated by the above equation, a dose of 1 Mrad will yield 1 millimole of total RPs per kilogram of irradiated food. Assuming an average RP molecular weight of 300, one kilogram of food irradiated at 1 Mrad will contain only 300 mg of newly formed chemicals.

TABLE 1

ESTIMATES OF RADIOLYTIC PRODUCTS IN IRRADIATED FOODS

Radiation Dose (krad)	G_T (Events/100eV)	(a)Yield of all RPs in Food (mmol/kg)	Yield of all RPs if MW=300 (mg/kg)	(b)Yield of URPs (mg/kg)
10	1	0.01	3	0.3
50	1	0.05	15	1.5
100	1	0.10	30	3.0
1,000	1	1	300	30

(a)-Yield (in mmol/kg) = Dose (krad) x $G_T \times 10^{-3}$
(b)-Assumes only 10% of RPs are unique (see text)

UNIQUE RADIOLYTIC PRODUCTS

While the yield of total RPs from a given irradiation dose may be substantial in toxicological terms, only unique radiolytic products (URPs) should be of concern. For example, increases in the fatty acid or amino acid content of a food due to the radiation induced break-down of triglycerides and proteins simply increase the amount of food constitutents normally present.

Unique radiolytic products, although defined here as substances not found in the unirradiated food, may also be common constitutents in the human diet. The true extent of the dietary "uniqueness" of URPs is somewhat tenuous, due largely to the paucity of information on the composition of both processed and unprocessed foods at the parts per million level. It is quite possible that radiolytic compounds now classified as unique in irradiated foods also occur in foods which have been processed by conventional thermal methods. Examination of the most complete set of available data on RPs in food will serve to illustrate and document the significance of distinguishing between total RPs and URPs. The U.S. Army's high-protein food sterilization program provides detailed analysis of volatile species identified in raw beef irradiated at 5 Mrad[8,9]. These volatiles consist of a nearly homologous series of 65 RPs derived primarily from the radiolysis of the triglycerides from the beef lipid fraction. Of the 65 volatiles, 23 were also identified in the thermally sterilized control, so that 42 were unique to the irradiated product (URPs). However, of these 42 URPs only six could not be identified in the volatile fractions of other nonirradiated foods[10]. Thus, only some 10% of this particular subset of RPs (the 65 volatiles) are in fact URPs. The structures of these six URPs are typical of the molecules identified as occurring in other food volatiles, and are similar to natural food consitituents.

Although, this example is taken from a series of RPs which happen to be associated with a volatile fraction of irradiated food, there is no apparent reason to believe that they do not also typify the relationship of non-volatile RPs and URPs to one another, and to the fraction of RPs which are consitutents to be found in other non-irradiated foods. Certainly some URPs will be formed which are structurally atypical of parent food molecules. Such URPs may be free radical coupling products of lipid and protein derived radicals, forming various coupling compounds, dimers, and cross-linked products. However, enzymatic hydrolysis by digestive enzymes is expected to process the majority of such URPs to yield normal molecular subunits, such as the fatty acids, amino acids, monosaccharides, and further subunits of these components, which would have resulted from the normal digestion of the orginal parent molecules.

Additionally, comparisons have been made on the types of RPs formed in irradiated fats with the thermal products formed in heated or thermally oxidized fats. These studies also indicate considerable product similarities. Thermal decomposition products from fatty acids, triglycerides, and fatty acid methyl esters produce a spectrum of n-alkanes, 1-alkenes, ketones, aldehyes, lactones, dimeric hydrocarbons, alcohols, CO_2, CO, H_2, and dimer acids and esters[11]. The dimeric compounds identified in heated methyl oleate were found to be structurally quite similar to dimers produced by irradiation of potassium oleate.

From the above considerations, it is reasonable to assume that the URPs constitute 10 percent or less of the total radiolytic product yield. The last column in Table 1 shows the expected quantity of total URPs at various irradiation doses.

1980 POLICY RECOMMENDATIONS

The Committee's main task was: to establish those toxicologic testing requirements appropriate for assessing the safety of irradiated food, where the degree of testing is compatible with the potential risk as indicated by the level of human exposure. Based on what we have learned from our review of all aspects of food irradiation, it is apparent that any toxicological testing requirements must also be predicated on the amounts of new chemical constituents generated by the irradiation process (URPs). Hence, the components of any new policy for assessing the safety of irradiated food are: 1) projected levels of human exposure; 2) qualitative and quantitative estimates of URPs; and 3) state-of-the-art sensitive toxicological tests.

While numerous efforts to estimate food consumption have been made, it is generally recognized that no single approach provides sufficiently accurate data. Hence, our projection of human exposure to irradiated foods will necessarily suffer the same limitations. The committee utilized estimates of a) total food consumption, b) dietary items proposed for irradiation and, c) the percent of each dietary item which may be irradiated. (See Human Exposure, Appendix III). These factors will vary with the specific food under consideration; however, a rough estimate based on these factors suggests that 10% of the total diet may consist of irradiated food in the near future.

Calculations based on radiation chemistry clearly indicate that irradiation doses of 100 krad or less yield a concentration of total radiolytic products in food that is so limited that it would be difficult to detect and subsequently measure potential toxicological properties. In addition, at this dose unique radiolytic products will be on the order of 3 ppm, and since the number of individual URPs is likely to be greater than ten, the amount of any particular URP will be considerably less than 1 ppm. Finally, our estimates of URPs may be exaggerated.

Hence, because of the low level of total unique radiolytic products produced, it is concluded that food irradiated at doses not exceeding 100 krad is wholesome and safe for human consumption. This rationale is based solely on an estimate of the concentration of individual URPs produced by the radiation dose to the food, and pertains even if a high proportion of the total human diet is irradiated at 100 krad. However, there are foods, such as spices, which comprise only a fraction of a percent of the human diet. It can be calculated that a food which comprises 0.01 percent of the diet and is irradiated at doses up to 5 Mrad will contribute radiolytic products to the daily diet at a level lower than a food comprising a significant fraction of the diet and irradiated at 100 krad (see Table 1). Consequently, foods comprising no more than 0.01 percent of the daily diet and irradiated at 5 Mrad or less will also be considered to be safe for human consumption without toxicological testing. This recommendation based on anticipated levels of human exposure, is consistent with the charge to the Committee.

The proposed general policy concerns the single irradiation of raw commodities. Selected instances of food irradiation may present novel considerations: for instance, a petition for a processed food may be received where one or more of the constituent raw commodities has been previously subjected to irradiation. Since it not possible, at this time, to predict the situations where such conditions may occur, they must be considered on a case by case basis.

TESTING

Foods irradiated at doses above 100 Krad and comprising more than 0.01% of the diet are estimated to contain URPs in sufficient quantity to warrant toxicological evaluation. The non-mammalian mutagenicity tests offer a level of sensitivity not practically attainable in whole animal tests, and recalling that many URPs may be similar chemically to substances occurring naturally in foods, these tests are considered appropriate tools to evaluate the potential carcinogenicity of irradiated foods. The tests recommended are 1) gene mutations in bacteria, with and without metabolic activation, 2) gene mutations in cultured mammalian cells, 3) DNA repair in mammalian cells, and 4) recessive lethal mutations in Drosophila. These test are considered to be the minimum battery. Requests for substitutions for any of the above tests should be justified and will be considered on a case by case basis.

Because of the anticipated low level of individual radiolytic products present in the whole irradiated food, the above tests must be performed on extracts in which the concentration of radiolytic products is maximized. Also, many of the radiolytic products from polysaccharides and proteins will be large molecules and will not penetrate the cell membrane in the *in vitro* systems, hence the use of enzyme digests is recommended prior to the concentration of URPs.

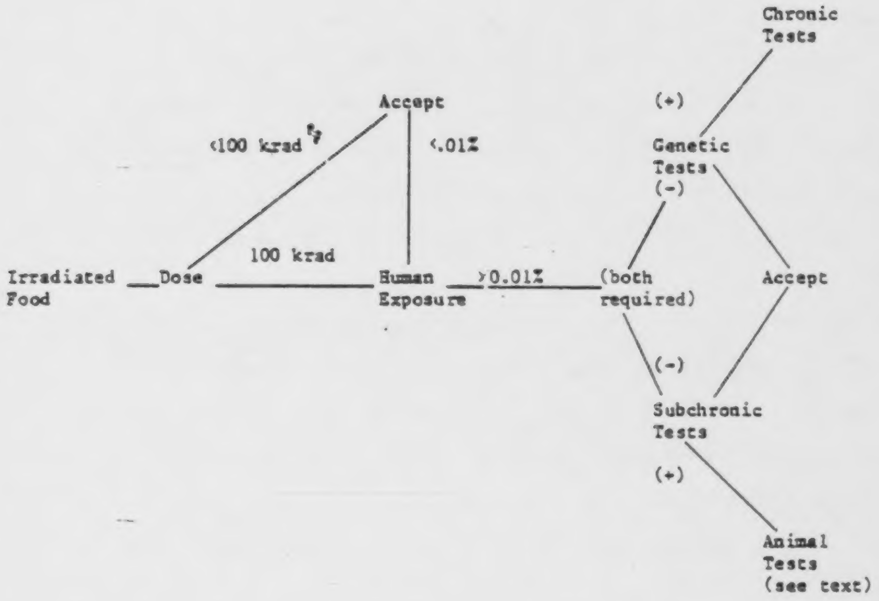
In addition to the short-term mutagenicity tests, foods irradiated at doses above 100 krad must be evaluated in 90-day feeding studies in two species (one rodent, one non-rodent). The 90-day rodent test should include in utero exposure. To assure that the test animals are exposed to the highest concentration of radiolytic products possible, the irradiated food may be lyophilized and incorporated into the animal diet at the highest concentration that does not compromise the nutritional requirements of the test species (see Appendix IV). It is not necessary to test enzyme digests of the irradiated food in these tests since each test animal provides digestion of food components before systemic absorption occurs. Higher doses of particular radiolytic products may be obtained if the selectively extracted and concentrated material used in the short-term tests is employed; however, it is recognized that much greater quantities would be needed for in vivo testing and thus would make this latter suggestion extremely difficult and expensive to effect in any practical sense.

CRITERIA

Unequivocal negative responses in the required tests will be sufficient to establish the safety of the irradiated food under test. Positive responses obtained in either or both of the types of required tests may trigger additional evaluation. Positive mutagenic responses suggest potential carcinogenicity and hence would necessitiate the performance of the chronic mammalian bioassay tests. The minimal requirements for positive mutagenic effect is the observation of positive responses in at least two of the short-term test systems. The rationale for requiring two positives is to reduce the probability of conducting further tests on the basis of a false positive or a species specific response. The results obtained in the chronic tests would either confirm or negate the positive results obtained in the short-term tests battery regarding the carcinogenic potential of the irradiated food; and, the results obtained in the chronic tests would be considered to be definitive.

In the 90-day studies, a variety of toxicological endpoints are evaluated and it is not possible *a priori* to determine what follow up tests may be required. Such decisions can only be made upon evaluation of actual test results. If the results obtained from the studies indicate teratological or reproductive effects, then the irradiated food must undergo teratological testing and/or reproductive testing via a three generation reproduction study. The overall procedures for establishing the safety of an irradiated food is displayed in Figure 2.

Figure 2 Safety Decision Tree


Chronic Tests
Accept
(+)
<100 krad
<.01%
Genetic Tests
(-)
100 krad
Irradiated Food
Dose
Human Exposure
>0.01%
(both required)
Accept
(-)
Subchronic Tests
(+)
Animal Tests (see text)

GENERIC

The earlier section on radiation chemistry discussed the generalization that the RPs formed are more a function of the chemical composition of the food than the irradiation dose. Thus, foods of a similar chemical composition would be expected to generate structurally similar radiolytic products. Therefore, when two or more foods are of sufficient similarity with respect to both chemical composition (lipids, carbohydrates, proteins and water content) and conditions of irradiation, they may be viewed in a generic sense for regulatory purposes. Comparability of radiation conditions is dependent upon the respective radiation dose, produst temperature and ambient atmosphere during irradiation. Hence, toxicologial data obtained from a given irradiated food item may be applicable for another irradiated food in the same generic class. In addition, safety data collected from food irradiated at high doses are applicable to members of the same generic class receiving a lower dose[12].

This generic policy is an extension of the principles set forth in the general policy for evaluating the toxicity of irradiated foods and is based upon the significant research which has been conducted in the areas of food chemistry and the chemistry of radiolytic products.

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APPENDIX I

COMMITTEE CHARGE AND RELATED MATERIAL

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Sanford A. Miller, Ph.D.
Director, Bureau of Foods HFF-1
Through: Dr. Albert C. Kolbye ACK
Associate Director for Sciences HFF-100

DATE: September 7, 1979

FROM : Herbert Blumenthal, Ph.D.
Director, Division of Toxicology HFF-150

SUBJECT: Establishment of a Committee to review, evaluate, and recommend criteria for safety evaluation of irradiated food.

Need

As you are undoubtedly aware, interest in food irradiation has been increasing recently. The USDA is seriously considering sponsorship of a food irradiation program that is now being conducted by the Army. They see potential for radiation replacing nitrite as a preservative in bacon and possibly other cured meats. There is a significant potential for radiation replacing ethylene oxide and ethylene dibromide, which are currently used as fumigants for fruits and spices. Both fumigants pose toxicological problems. The USDA, the EPA, as well as industry people have contacted us regarding these potential uses.

Although various clearances for irradiated foods have been sought since the 1960s, and although considerable resources have been expended in trying to establish the safe use of irradiated foods, there has been little in the way of positive regulatory response. Instead, petitioners have been frustrated by what they perceive as a continuation of often excessive regulatory requirements and our scientists have been frustrated by what they perceive as poor and inadequate data with which to evaluate safety. In light of what has obviously been a failure in understanding and because of our changing views about toxicologic requirements coupled with the unique problems associated with the toxicologic evaluations of food commodities and the likelihood of increased activity in the Bureau of Foods regarding food irradiation, we recommend that a committee be appointed to reevaluate and determine criteria, consistent with current toxicological knowledge, to assess the safety of irradiated foods.

Reason

In 1958, Congress declared a source of radiation to be a food additive for purposes of the food additives amendment. Early safety studies were based on principles of traditional toxicological testing appropriate for food additives. Two problems were encountered: food could not be irradiated at high dosages to obtain a safety factor without drastically changing the product; and testing the food itself at mildly exaggerated levels can lead to unphysiological diets.

Many millions of dollars have been spent in the intervening twenty years, particularly by the U. S. Government, to improve the technology and to demonstrate the safety of these irradiated foods. The FDA outlined tha type of information needed to demonstrate safety in May 1967. Yet, after all these years of effort only a few minor uses of food irradiation have been approved and those approvals occurred before the 1967 FDA guidelines were issued. The result of most studies was neither a demonstration of safety nor a discovery of potential problems, but another compilation of work whose results could not be conclusively assessed.

Although many of the early failures to achieve regulatory approval of irradiated foods can be attributed to studies which display problems of laboratory performance, more recent studies have suffered from an overwhelming complexity of design. Such changes in experimental design have been made on a more or less ad hoc basis without a full reassessment of the whole range of irradiation and irradiated foods. In light of the new interest in irradiation as a solution to some current food additive and pesticide problems, we feel that it is an appropriate time to reassess whether the requirements for demonstrating safety, outlined in 1967, are the best way of addressing the safety questions consistent with today's knowledge and with the peculiar problems posed by irradiated foods.

Purpose

The purpose of the committee will be to guarantee a full reassessment of all cogent issues applicable to irradiated food. To accomplish this full reassessment, we recommend establishment of a committee of scientists who have not previously played a significant role in development of FDA policy on irradiated food. This committee would profit from the application of a fresh outlook uncolored by the bias of past involvement but at the same time it would be expected to draw on the resources of those people who have had the background and experience for having been deeply involved with FDA irradiated food policy.

Scope

The scope of this committee will be:

1. To review current policy and critical aspects of its past implementation,
2. To examine the foundation and soundness of that policy, and
3. To establish those toxicologic requirements appropriate for assessing the safety of irradiated food consistent with the level of human exposure, where the degree of testing is consistent with the potential risk as predicated on the level of human exposure. These requirements would be analogous to, and consistent with, the philosophy supporting the Cyclic Review of direct additives.

Function

1. To acquaint themselves with the problem by reading appropriate documents, hearing presentations, and questioning persons knowledgeable in this area. (Month 1).
2. To plan an approach for completing the task and submitting it to the Division of Toxicology. (Month 2).
3. To provide a draft report of conclusions to the appropriate Divisions. (Month 6).
4. To submit a final report (May 1980).

Structure

We have designated the following scientists from the Division of Toxicology for this committee:

(1) Dr. Lawrence Valcovic, HFF-170 (Chairman)
(2) Dr. William Greear, HFF-180
(3) Dr. David Hattan, HFF-185

We are also requesting a representative from:

(4) The Division of Chemistry - to address questions on radiolytic products formed and the effect of variables in the process (dose, temperature, air, matrix).

(5) The Division of Nutrition - to address questions on radiation effects on nutrients.

(6) The Division of Food and Color Additives - to assure that all significant issues and resources are identified, and to serve as Executive Secretary. (We understand that Mr. Richard Ronk has designated Dr. Clyde Takeguchi for this role).

We expect the committee will need to draw on the resources of the Division of Microbiology and the Division of Food Technology from time to time, but nothing extensive is anticipated at this time.

Resources

We believe that the complexities and critical nature of this task will require a large commitment of time from persons on this task force, occasionally ranging as high as 50%. It will also require a lesser amount of time from resource people on whom the committee will draw. We expect the need for some monetary assistance to bring in outside consultants with special areas of expertise.

Recommendation

We recommend that authorization be given to appoint this committee and charge the members with their task.

Herbert Blumenthal, Ph.D.

RECOMMENDED COURSE OF ACTION

DECISION

Approved________________ Disapproved________________ Date 9/10/79

Resource Persons

A. **Interviews**

FDA

H. Blumenthal	HFF-150
W. G. Flamm	HFF-152 (SOM)
J. Modderman	HFF-458
K. P. Misra	HFF-156
M. Bleiberg	HFF-156
C. Kokoski	HFF-156
T. Troxell	HFF-334 (Constituents)
A. Rulis	HFF-334 (Risk Assessment)
F. E. Scarbrough	HFF-334 (Cyclic Review)
R. B. Read	HFF-230

Natick

A. Brynjolfsson
E. Wierbicki
I. Taub
C. Merritt
M. Simic (presently with NBS)

B. **Meeting**

Contractors' Meeting at Natick, 9-11 January 1980
Attended by Brunetti, Takeguchi and Valcovic.

C. **Communications**

Letters

P. Elias, International Project in the Field of Food Irradiation, Germany.

W. Urbain, FDA Consultant, Sun City, AZ.

E. Sickel, European Gnotobiotic Association.

D. deZeeuw, Ministerie Van Landbouw, Visserij, Netherlands.

Phone

Thomas Burns, American Spice Trade Association.

Irwin Taub, Natick, MA.

John G. Beri, Nutritional Biochemistry Section, NIH, NIAMDD.

Jack Schubert, Hope College, MI.

W. Urbain, FDA Consultant, AZ.

APPENDIX II

NUTRITIONAL ADEQUACY

Many of the requirements to demonstrate the nutritional safety and adequacy of an irradiated food that were specified in the 1967 FDA document are still valid and, consequently, remain basically unchanged. New "1980" criteria for the safety evaluation of the nutritional adequacy of irradiated food, as contained in this section, essentially consist of a clarification or expansion of the 1967 document. New general or specific recommendations made elsewhere in this document, which are different from those made by the Division of Nutrition in the 1967 document, supercede the older recommendations or guidelines. Under the current organizational structure within the Bureau of Foods of FDA, assessment of nutritional factors in food additive petitions, including those for irradiated foods, are examined by the Division of Nutrition which is part of the Office of the Associate Director for Nutrition and Food Sciences.

In keeping with one of the functions of the Division of Nutrition, namely, to develop and recommend regulatory approaches to maintain or improve the nutritional quality of the national food supply, any petition for approval of an irradiated food should provide supporting data to demonstrate that the levels of characterizing nutrients, particularly essential nutrients, will be either maintained or improved in comparison to an existing process that the irradiation process would replace. For example, it should be shown that the protein, thiamin, and other key nutrients in irradiation sterilized beef are comparable to those in a thermally processed product. On the other hand, there would be little concern if an appreciable reduction in vitamin C content were to occur since the product, sterilized beef, contains an insignificant amount of the vitamin and would not normally be regarded by the consuming public as a good source for this particular vitamin. Where there is no appropriate process to serve as a base for comparison, the effects of the petitioned process on the quality of the product will be assessed on a case-by-case basis taking into consideration economic and other factors. These conditions do not, however, diminish the importance of the two-part question in the 1967 document which listed the following as foci with regard to the nutritional aspects of an irradiated food: 1) if a food is an important source of one or more nutrients or nutritional properties or qualities essential for optimum health in any diet, does the proposed irradiation treatment of the food cause it to be adulterated or devalued such that it is nutritionally inferior to the unirradidated food?; and 2) if yes, does it pose a potential public health nutrition risk for individuals in the population? It is to be noted that the first part of the above question would more appropriately involve a comparison, within reason, between an irradiated food and the food treated by a conventional process. This is regarded to be more appropriate than, but should not completely supplant, an evaluation of the nutritional qualities of a food before and after irradiation.

In the 1967 policy statement, nutritional quality was stated to include the following:

1. vitamin content, stability, and physiological availability,
2. fat content, quality and essential fatty acid composition,
3. protein quality,
4. digestibility of fat, carbohydrate, and protein components of a food, and the availability of the potential biological energy derived from them,
5. the absence of anti-metabolites,
6. the absence of toxic degradation products of radiation-sensitive nutrients and nutritional adjuncts (for example, carrageenan, starch, emulsifiers, artificial sweeteners, EDTA), and
7. the subjective qualities of food that make it desirable to eat, such as color, flavor, texture, and masticatory and hunger satisfaction.

These continue to be regarded as appropriate factors for determining nutritional quality with a qualification that an assessment of the absence of the toxic degradation products of radiation-sensitive nutrients and food adjuncts is primarily a matter for toxicological rather than nutritional review.

From a number of studies on the radiation stability of vitamins, protein, fat and other nutrients, it is known that several nutrients are sensitive to ionizing radiation. This sensitivity, however, depends not only upon the nature and composition of the food system, but also on a number of controllable factors such as dose, temperature of the product being irradiated, and the relative presence or absence of oxygen in the product during irradiation. Hence, the destruction of labile nutrients can be minimized by careful selection of the conditions for irradiation. Several reviews have been published that deal with the effects of irradiation on the nutritional aspects of food[1,2,3]. Some of the macronutrient components - amino acids such as cystine, methionine and tryptophan, for example - are more sensitive to irradiation than others. The amounts that are destroyed, however, are usually insignificant compared to the unirradiated food or to a product treated by a conventional process. Studies with radiation sterilized beef and radiation pasteurized chicken show little or no change in content of specific amino acids, amino acid availability and protein efficiency ratio[1].

Concerns in the past regarding the formation of an antithiamin factor in irradiated food are not supported by recent studies. A report by McGowan and associates[4] indicates that irradiated chicken and thermally processed chicken are equally effective in repleting thiamin-dependent blood enzyme levels in thiamin-deficient rats. Even so, there is ample published evidence that a number of vitamins are labile to some degree when irradiated. Particular attention should be focused on vitamin A and carotene, vitamin E, vitamin C, vitamin B-12, thiamin, and vitamin B-6. Although other vitamins and essential nutrients must not be ignored, the aforementioned vitamins are noted because of published studies that demonstrate losses in irradiated products.

As stated in the 1967 document, a petition should assure that the petitioned radiation process is sound from a nutritional standpoint by satisfactorily demonstrating that the irradiated product is nutritionally safe and efficacious. In that document, an inference was made that compensation for the destruction or alteration of nutritional factors would not be excluded from consideration during a petition review. To make this policy more explicit, restoration of a labile nutrient will be given consideration if the irradiation process has the potential to be highly advantageous for public health, economic, or other reasons such as the extended availability of seasonal or highly perishable products.

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APPENDIX III

HUMAN EXPOSURE

FACTOR I: FOOD CONSUMPTION FACTORS

Ideally, food consumption factors should be based on the quantity of food actually consumed. Such data are not currently available for most dietary items; however, a recent survey conducted by the United States Department of Agriculture (U.S.D.A.) is now being analyzed by the Division of Nutrition. In the past, U.S.D.A. has published data on food consumption based on retail weights[1] and household surveys[2]. The retail weight food consumption data are calculated from agricultural production figures and estimated loss during distribution. The household survey data are based on personal interviews with household members and reflect food consumption measured at the level at which foods enter the kitchen. Because the household survey data more closely reflect actual consumption than the retail weight data, the household survey data were used to generate Table 1 which is currently in use by the Environmental Protection Agency (EPA) for tolerance setting purposes. This table will be used, in the interim, to estimate the human exposure to irradiated food.

Table I

Average Food Factors

Crop	% diet	lbs/wk/household	grams/person/day
Almonds	0.03	0.03	0.59
Apples	2.53	2.48	50.13
Apricots	0.11	0.11	2.23
Artichokes	0.03	0.03	0.59
Asparagus	0.14	0.14	2.84
Avocados	0.03	0.03	0.59
Bananas	1.42	1.39	28.15
Barley	0.03	0.03	0.59
Beans	2.04	2.00	40.42
Beans,dry edible	0.31	0.30	6.14
Beans,lima	0.19	0.19	3.77
Beans,snap	0.98	0.96	19.44
Beet greens	0.03	0.03	0.59
Beets	0.17	0.17	3.44
Blackberries	0.03	0.03	0.59
Black-eyed peas	0.03	0.03	0.59
Boysenberries	0.03	0.03	0.59
Blueberries	0.03	0.03	0.59
Broccoli	0.10	0.10	2.03
Brussel Sprouts	0.03	0.03	0.59
Buckwheat	0.03	0.03	0.59
Cabbage,sauerkraut	0.74	0.72	14.58
Cantalopes	0.52	0.51	10.33
Carrots	0.48	0.47	9.52
Casabas	0.03	0.03	0.59
Cattle	7.18	7.03	142.37
Cauliflower	0.07	0.07	1.42
Celery	0.29	0.28	5.67
Cheese	1.12	1.10	22.28
Cherries	0.10	0.10	2.03
Chicken	2.58	2.52	51.03
Chicory	0.03	0.03	0.59
Citrus Fruits	3.81	3.73	75.54
Cocoa	0.12	0.12	2.38
Coconut	0.03	0.03	0.59
Coffee	0.75	0.73	14.78
Collards	0.08	0.08	1.62
Corn	2.52	2.47	50.02
Corn,pop	0.08	0.08	1.62
Corn,sweet	2.25	2.20	44.55
Cottonseed	0.15	0.15	2.97
Crabapples	0.03	0.03	0.59
Cream	0.13	0.13	2.63
Cranberries	0.03	0.03	0.59
Crenshaws	0.03	0.03	0.59
Cucumbers,inc pickl	0.73	0.71	14.38
Cucumbers,not pickl	0.34	0.33	6.68

Table I (Continued)

Crop	% diet	lbs/wk/household	grams/person/day
Currants	0.03	0.03	0.59
Curcurbits	2.84	2.78	56.30
Damsons	0.03	0.03	0.59
Dates	0.03	0.03	0.59
Dewberries	0.03	0.03	0.59
Eggplant	0.03	0.03	0.59
Eggs	2.77	2.71	54.89
Elderberries	0.03	0.03	0.59
Escarole	0.03	0.03	0.59
Figs	0.03	0.03	0.59
Filberts	0.03	0.03	0.59
Fish,shellfish	1.08	1.06	21.47
Fruiting Vegetables	2.99	2.93	59.34
Garlic	0.03	0.03	0.59
Goats	0.03	0.03	0.59
Gooseberries	0.03	0.03	0.59
Grain Crops	13.70	13.41	271.57
Grapefruit	0.99	0.97	19.64
Grapes, inc raisins	0.49	0.48	9.72
Grapes, not raisins	0.45	0.44	8.91
Greens	0.03	0.03	0.59
Hogs	3.43	3.36	68.04
Honey	0.06	0.06	1.22
Honeydewmelons	0.03	0.03	0.59
Honeyballs	0.03	0.03	0.59
Hops	0.03	0.03	0.59
Huckleberries	0.03	0.03	0.59
Kale	0.03	0.03	0.59
Kohlrabi	0.03	0.03	0.59
Horseradish	0.03	0.03	0.59
Jer Artichokes	0.03	0.03	0.59
Kumquats	0.03	0.03	0.59
Leafy Vegetables	2.76	2.70	54.68
Leeks	0.03	0.03	0.59
Lemons	0.17	0.17	3.44
Lentils	0.04	0.04	0.81
Lettuce	1.31	1.28	25.92
Limes	0.17	0.17	3.44
Loganberries	0.03	0.03	0.59
Macadamia nuts	0.03	0.03	0.59
Mangoes	0.03	0.03	0.59
Meat,all	13.85	13.55	274.41
Meat, red	10.81	10.58	214.26
Meat,game	0.09	0.09	1.82
Melons	2.00	1.96	39.69
Milk&Dairy Products	28.62	28.00	567.04
Millet	0.03	0.03	0.59
Milo	0.03	0.03	0.59
Molasses	0.03	0.03	0.61
Mushrooms	0.03	0.03	0.59

Table I (Continued)

Crop	% diet	lbs/wk/household	grams/person/day
Muskmellons	0.03	0.03	0.59
Mustard Greens	0.06	0.06	1.22
Nectarines	0.03	0.03	0.59
Nuts	0.10	0.10	2.03
Oats	0.36	0.35	7.09
Okra	0.07	0.07	1.42
Olives	0.06	0.06	1.22
Onions	0.83	0.81	16.40
Onion(dry bulb)	0.72	0.70	14.18
Onions,green	0.11	0.11	2.23
Oranges	2.17	2.12	42.93
Papayas	0.03	0.03	0.59
Parsley	0.03	0.03	0.59
Parsnips	0.03	0.03	0.59
Passion fruit	0.03	0.03	0.59
Pawpaws	0.03	0.03	0.59
Peaches	0.90	0.88	17.82
Peanuts	0.36	0.35	7.09
Pears	0.26	0.25	5.06
Peas	0.69	0.68	13.77
Pecans	0.03	0.03	0.59
Peppermint	0.03	0.03	0.59
Peppers	0.12	0.12	2.43
Persion Melons	0.03	0.03	0.59
Pimentos	0.03	0.03	0.59
Pineapple	0.30	0.29	5.87
Plums,not prunes	0.09	0.09	1.82
Plums,inc prunes	0.13	0.13	2.63
Pome Fruits	2.79	2.73	55.29
Potatoes	5.43	5.31	107.34
Poultry	2.94	2.88	58.32
Poultry,exc chic&tur	0.04	0.04	0.81
Prunes	0.04	0.04	0.81
Pumpkin,inc squash	0.11	0.11	2.23
Quinces	0.03	0.03	0.59
Radishes	0.03	0.03	0.59
Raisins	0.04	0.04	0.81
Raspberries	0.03	0.03	0.59
Rhubarb	0.05	0.05	1.01
Rice	0.55	0.54	10.94
Root Crop Veg	11.00	10.76	217.91
Rutabagas	0.03	0.03	0.59
Rye	0.03	0.03	0.59
Safflowwer	0.03	0.03	0.59
Salisfy	0.03	0.03	0.59
Seed&Pod Veg	3.66	3.58	72.50
Shallots	0.03	0.03	0.59
Sheep	0.19	0.19	3.85
Small Fruit,berries	0.83	0.81	16.40
Sorghum	0.03	0.03	0.59

Table I (Continued)

Crop	% diet	lbs/wk/household	grams/person/day
Soybeans	0.92	0.90	18.19
Spearmint	0.03	0.03	0.59
Spinach	0.05	0.05	1.01
Stone Fruits	1.25	1.22	24.71
Strawberries	0.18	0.18	3.65
Sugar Beet Tops	0.03	0.03	0.59
Sugar,cane&beet	3.64	3.56	72.10
Summer Squash	0.03	0.03	0.59
Sunflower	0.03	0.03	0.59
Sweet Potatoes	0.40	0.39	7.90
Swiss Chard	0.03	0.03	0.59
Tangelos	0.03	0.03	0.59
Tangerines	0.03	0.03	0.59
Taro	0.03	0.03	0.59
Tea	0.07	0.07	1.42
Tomatoes	2.87	2.81	56.97
Turkey	0.33	0.32	6.48
Turnips	0.05	0.05	1.01
Turnip Greens	0.03	0.03	0.59
Walnuts	0.03	0.03	0.59
Water Cress	0.03	0.03	0.59
Watermelon	1.43	1.40	28.35
Wheat	10.36	10.14	205.35
Wintersquash	0.03	0.03	0.59
Youngberries	0.03	0.03	0.59

FACTOR II: DIETARY ITEMS SUBJECT TO IRRADIATION

In the United States only two items are currently approved for irradiation: wheat and potatoes. In December, 1979, a draft of the Codex Alimentarius Commission's Recommended General Standard For Irradiated Foods proposed that irradiation be approved for certain dietary items. These dietary items and the percent contribution to the diet are listed below in Table II. A variety of dietary items are being tested to determine the feasibility of irradiation as a practical method of food preservation[3]. These dietary items and the percent contribution to the diet are listed in Table III. In the future, irradiation of certain dietary items listed in Table III may not prove to be feasible and thus will not constitute a source of human exposure. However, it appears equally likely that research in the area of food irradiation may demonstrate a need and/or an economic advantage of irradiation as a means of food preservation of other dietary items.

TABLE II. Foods Recommended by Codex for Irradiation

Dietary Item	Percent of the Diet
Potatoes	5.43
Onions	0.83
Papaya	0.03
Strawberry	0.18
Wheat	10.36
Cod and Red Fish	1.08*
Chicken	2.58
Rice	0.55
	21.04 Total

*-Data were available for the category fish and shellfish only; therefore, the figure may be overestimated.

Table III. Other Foods Considered for Irradiation

Dietary Item	Percent of the Diet
Mushroom	0.03
Spices	*
Garlic	0.03
Shallots	0.03
Asparagus	0.14
Cocoa Beans	0.12
Shrimp	*
Endive	*
Mango	0.03
Grain (excluding wheat)	3.34
Beef	7.18
Pork	3.43
Rabbit	*
Dried Fruit	*
Tomato	2.87
Peach	0.90
Apricot	0.11
Cherry	0.10
Raspberry	0.03
Grape	0.45
	18.79 Total

* -Data are not available on these dietary items

FACTOR III: IRRADIATION OF INDIVIDUAL DIETARY ITEMS

Although, wheat and potatoes have received approval for processing by irradiation in the United States, commercial operations for irradiating these dietary items are nonexistent in this country. Therefore, the question arises: To what extent will individual dietary items be subjected to processing by irradiation? For example, mangoes will probably only be irradiated for disinfestation for export purposes. Fresh fish intended for local consumption may not be irradiated; however, fish intended for shipment to other parts of the country may be irradiated in order to extend shelf life. At present, there are no reliable data available to indicate to what extent any individual dietary item will be irradiated. Thus, it is conservatively assumed that if a dietary item is approved for irradiation, the proportion of the diet constituted by that dietary item will be 100 percent irradiated.

In summary, the United States has approved irradiation for two major dietary items constituting approximately 16 percent of the diet, but neither is commercially being irradiated in the United States. The Codex Alimentarius Commission will, in the near future, propose that dietary items representing 21 percent of the diet be approved for irradiation. Taking into account the ever changing dietary habits of the United States population, the various dietary items that could be approved for irradiation, and the percentages of these dietary items which would actually be irradiated, it is difficult to predict, with any degree of accuracy, the actual amount of irradiated food to which the population will be exposed in the forseeable future. A worst-case estimate would predict that 40 percent of the human diet would consist of irradiated food (Table II plus Table III).

However, from a practical point of view, it is anticipated that the actual human exposure will probably not exceed 10 percent of the diet in the near future. This rough estimate is based on the following factors: 1) many years will be required to develop commerical food irradiation facilities for the mass processing of irradiated foods, 2) not all food approved for irradiation will be irradiated due to economic comparison with other competing techniques used in food processing, e.g. canning and refrigeration and, 3) consumer acceptance of irradiated food versus non-irradiated food is expected to be low, initially, due to the stigma associated with the term "irradiation." A program instituted by the government or private industry in an attempt to educate the public, with respect to the safety of irradiated foods, may encounter considerable resistance on the part of the consumer. Thus, irradiation of major dietary items may not be acceptable as an alternative method of food processing for many years. Irradiation of minor dietary items such as spices may be acceptable to a greater extent than irradiation of major dietary items because of the lower perceived risk involved in their limited use.

References

1. Food Consumption, Prices, Expenditures. Supplement for 1975 to Agricultural Economic Report No. 138; U.S. Department of Agriculture, Economic Research Service, January, 1977.

2. Household Food Consumption Survey, 1965-66, Report No. 12; Food Consumption of Households in the United Sates, Seasons and Year 1965-66, U.S. Department of Agriculture, Agricultural Research Service, March, 1972.

3. Food Irradiation Newsletter Vol. 1, No. 3, pp. 34-39, November 1, 1977 and Vol. 2, No. 1, page 45, March, 1978.

APPENDIX IV

ANIMAL DIET CONSIDERATIONS

DIETARY RECOMMENDATIONS FOR CHRONIC FEEDING STUDIES WITH IRRADIATED FOODS

In those instances where chronic feeding or reproduction studies of an irradiated product prove necessary, it is important to be aware of a number of limitations which are inherent in the performance of chronic studies with irradiated foods. It is very difficult to feed exaggerated amounts of human foods to animals for the purpose of toxicity testing. When a test animal is fed abnormally large amounts of certain foods or macronutrients; e.g., protein or fats, on a chronic basis, the test species become susceptible to nutritional disorders, or organ failure which may in turn result in premature morbidity and/or mortality of the test animals. This particular difficulty is exemplified by chronic feeding studies in the recent past which have substituted up to thirty-five percent of the normal diet with specific irradiated foods; e.g., beef, chicken, potatoes, onion, and papaya. The portion of the diet substituted (35%), did not provide the full complement of nutrients required and, in a number of instances, studies had to be terminated before completion because of premature mortality and/or morbidity.

Instead of merely substituting a portion of the normal diet with a given irradiated food, it is recommended that a new type of dietary regimen be developed. The new regimen would be based upon supplying those food components and amounts as designated by certain published semi-synthetic diets[1]. A balance should be established whereby the test species gets the maximum amount of irradiated food consistent with satisfaction of nutritional requirments. For example, up to fifteen percent of the rat diet might be protein derived from beef or chicken with small amounts of casein or certain amino acids added to fulfill the required amounts of individual amino acids as described in the semi-synthetic diets[1].

This technique would involve analytically identifying and measuring the various consitutents of a specified food to be irradiated then determining the maximum quantity which might be substituted into the synthetic diet mix, while still supplying all essential nutrients. It would be essential that development of the feeding protocols be carried out with the close consultation and advice of nutritional experts who are experienced at maintaining experimental animals in long-term studies with semi-purified diets[2]. In order to maximize the quantity of irradiated food added to the dietary mix, the foods following irradiation should be freeze-dried (lyophilized).

Lyophilization of the irradiated product will simplify its addition to the diet, since in this form it may be powdered and conveniently mixed with the other dietary components. Furthermore, this dehydration method would have the additional advantage of increasing the stability of the irradiated food (reduced potential for breakdown by microorganisms) and is less destructive than cooking. While it may be suggested that this method will not provide a means of testing volatile radiolytic products, in a practical sense, large amounts of these radiolytic products are lost during packaging, storage or preparation, and thus very small amounts are consumed. A low level of concern for these radiolytic products is also indicated by the fact that they are present even before packaging, storage or preparation only in the ppb range.

It is important that the semi-synthetic diet be palatable to the species being tested and thus, short-term, pilot feeding studies of the diet should be conducted to determine its acceptance. The caloric density (digestible energy) of the diet must be within the proper range. If the caloric density of the diet of rapidly growing rats is below 2.9 kcal per cubic centimeter of food, the weanling rat cannot meet its energy requirement and its growth rate is impaired[3]. The daily dietary intake of Sprague-Dawley female rats varies dramatically with functional state; i.e., non-pregnant 10 to 15 g, pregnant 20 g and lactating 30 to 35 g. Thus, the dietary demands of the test species will depend upon the type of testing. The nutritional demands of a reproductive or teratogenic study will obviously be different than those of a chronic toxicity study and these differences in nutritional requirements must be considered in the dietary regimen being developed.

Care must be taken to assure that excessive quantities of food components are not added to the diet. For instance, when rats were provided with a diet which was very high in protein (30 to 50% for 600 days), significant glomerulosclerosis was observed[4]. It is recommended that the following treatment groups be included in reproduction studies with irradiated food products 1) control group on normal laboratory diet, 2) control group on semi-synthetic diet, 3) control group on unirradiated food component supplemented to nutritional requirements by semi-synthetic diet, and 4) test group on irradiated food component supplemented to nutritional requirments by semi-synthetic diet. In other types of toxicity testing; e.g., chronic studies, a normal laboratory diet group may not be required[2].

References

1. Report of the American Institute of Nutrition Ad Hoc Committee on Standards for Nutritional Studies. J. Nutrit. 107:1340-8, 1977.
2. Memo of telephone conversation with Dr. J.G. Bieri, May 28, 1980.
3. Nutrient Requirements of Laboratory Animals, National Academy of Sciencies, Washington, D.C., 1978.
4. Bras, G. and Ross, M.H. Kidney Disease and Nutrition in the Rat. Tox. Appl. Pharmacol. 6:247-262, 1964.

Dr. **Miller**. In a similar manner, the international community has also attempted to evaluate the safety of irradiated foods. In the 1960's several organizations of the United Nations established a joint committee of experts knowledgeable in many disciplines to review the data and to make recommendations regarding this new processing method. Their recommendations have been published in a series of reports on various aspects of food irradiation. To a significant extent these deliberations—the deliberations of this expert committee—have tracked our own and have proceeded on a parallel course to our own activity.

We, of course, are considering these recommendations and the supporting data, but it is important to point out that our decisions have been based on our own review, which is what is required under the law.

As you know, FDA's special involvement in food irradiation is mandated by the Food Additives Amendment of 1958 which specifically includes sources of radiation in the definition of a food additive. Let me emphasize, Madam Chairperson, this is not a policy decision of FDA. This is in the act, and we are compelled to act in this direction.

This legislation requires premarket approval before a source of radiation may be used to process food, and states that a food is adulterated if it has been intentionally subjected to radiation unless there is a food additive regulation.

The proposal that the Agency published in February 1984 was preceded by several earlier actions concerning irradiation of food. A historical list is attached to my full statement for your review. As it will show, we permitted the use of irradiation for the control of insect infestation of wheat and wheat products since 1963, and the use of irradiation for sprout inhibition since 1964. And I might point out to you that these were among the first regulations in the world permitting the use of food irradiation.

Prior to the publication of our most recent proposal in February 1984, the Agency published an advanced notice of proposed rulemaking in 1981. That notice, as is the current proposal, was based on the current criteria for safety evaluation recommended by our irradiated foods committee, and was the first step in the administrative process which was intended to establish new operating criteria for evaluating safety data.

As you know, Madam Chairperson, this proposal permits the use of irradiation for sprout inhibition and shelf life extension of fresh fruits and vegetables, and for insect infestation of foods at doses not to exceed 100 kilorads. It also proposed the sterilization of spices at doses not to exceed 3 megarads, and I'd like to submit that proposal for the record.

Mrs. **Lloyd**. Without objection it will be included.

Dr. **Miller**. Thank you.

[Material to be supplied follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 81N-0004]

Policy for Irradiated Foods; Advance Notice of Proposed Procedures for the Regulation of Irradiated Foods for Human Consumption

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is considering proposing procedures for regulating irradiated foods. As a first step, FDA is making available to the public for comment the report of an internal agency task force, the Bureau of Foods' Irradiated Food Committee. The agency is publishing this notice to encourage interested persons to submit pertinent data and to express their views to aid in FDA's decisions on this subject. The preamble to any proposed procedures for the regulation of irradiated foods will include consideration of comments received in response to this notice.

DATE: Comments, information, and data by June 25, 1981.

ADDRESS: Written comments and material to the Dockets Management Branch (formerly the Hearing Clerk's office), (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Clyde A. Takeguchi, Bureau of Food (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:

Introduction

In 1958, the Congress amended the Federal Food, Drug, and Cosmetic Act (the act) prohibiting the use of a new food additive until the sponsor establishes its safety and FDA issues a regulation specifying conditions of safe use. This amendment was the result of an extensive examination of the safety of the American food supply and the recognition that substances added to food may have a potential harmful effect.

Congress also showed concern over a new method of food preservation with ionizing radiation and specifically included sources of radiation in the definitions of food additive (section 201(s)) and adulterated food (section 402(a)(7)) of the act. Section 201(s) states: "The term 'food additive' means *any substance* the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or *otherwise affecting the characteristics of any food (including any substance intended for use in* producing, manufacturing, packing, *processing,* preparing, *treating,* packaging, transporting, or holding *food; and including any source of radiation intended for any such use),* * * *" [emphasis added]. The adulteration clause, section 402(a)(7) states: "A food shall be deemed to be adulterated—* * * (a) * * * (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409." The specific inclusion of irradiated food in the amendment shows clearly that the FDA is responsible for regulating the use of irradiated foods by requiring a rigorous review of the potential hazards associated with this food treatment.

Background

Food irradiation may involve the following sources of ionizing radiation: gamma radiation from radionuclides, high energy electrons derived from electron beam accelerators, and X-rays. A variety of technical effects such as sprout inhibition, insect control, pasteurization, and food sterilization have been demonstrated.

These technical effects are a function of the absolute amount of energy absorbed by food (expressed as radiation dose in rads). In considering the safety of irradiated foods, the agency has considered both the induction of new radioactive species and production of toxic radiolytic products. The question of induction of new radioactive species was resolved in the early 1960's: the accumulated evidence shows that the use of ionizing radiation of appropriate source energy levels does not induce any detectable radioactivity in foods when measured by methods that can easily detect the presence of radioisotopes that occur naturally in foods. The question of the safety of radiolytic products is addressed in the Bureau of Foods' Irradiated Food Committee report. (A National Bureau of Standards paper, "Radioactivity Criteria for Radiation Processing of Foods" by H. W. Koch and E. H. Eisenhower, is on file with the FDA Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857 and may be seen from 9 a.m. to 4 p.m. Monday through Friday. The Bureau of Foods' Irradiated Food Committee report is also on file and copies are available on request from the Dockets Management Branch, (address above)).

Applications for food irradiation extend from low doses for limited shelf-life extension to high doses for complete sterilization of foods. Existing alternative methods for achieving these effects in foods require the use of a variety of chemical and physical means. For example, irradiation might be used as a substitute for food additives (nitrite), fumigants (ethylene dibromide, ethylene oxide), and plant regulators (maleic hydrazide), and as a food processing technique for food preservation (canning, pasteurization).

In the 1960's FDA received several petitions for regulation of irradiation processing for various types of foods. At present only irradiation for sprout inhibition of potatoes and insect disinfestation of wheat and wheat flour are approved, and there has been no commercial application of these approved uses.

There have been many difficulties encountered in the process of determining whether irradiated foods are safe. In the past, toxicological indices and protocols were applied to irradiated foods as if the whole irradiated food were a discrete chemical entity similar to a "conventional" food additive. This approach was based on section 409(c)(5)(A) of the act, which states: "In determining * * * whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—(a) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive; * * *." A major problem with the safety evaluation of irradiated foods was the lack of knowledge of the identity, amount, and toxicity of the radiolytic products formed in food by irradiation. Thus, irradiated food, a food containing unknown amounts of radiolytic products formed by the irradiation process, was tested for safety using chronic animal feeding studies.

Evaluating the safety of irradiated foods by such testing methods was impractical. for several reasons. The most significant problem was the limited ability to obtain a "safety factor" from a classical dose response curve obtained from animal feeding studies. Because irradiated food itself was considered the "chemical" to be tested in these studies. it was very difficult to feed the exaggerated amounts of food that are necessary for the purpose of traditional toxicity testing. For example. it is not possible to obtain a 100-fold safety factor if the food fed to animals is greater than 1 percent of the total human diet. It was further recognized in early studies that increasing the radiation dose (10x. 100x. etc.) as a means of exaggerating the amount of radiolytic products is not a viable alternative for practical as well as theoretical reasons.

The renewed interest in irradiation as a possible safe alternative to chemicals in food led the agency to review the complex issue of irradiated foods. An internal FDA task force. the Bureau of Foods's Irradiated Food Committee. was formed to evaluate the agency's policy on irradiated foods according to the current state-of-the-art knowledge in toxicology and radiation chemistry and to recommend criteria for safety evaluation. The Committee submitted its final report to the Director. Bureau of Foods. FDA. in August 1980.

The Committee has submitted the following recommendations:

a. Food irradiated at doses of 100 kilorads (krad) or less will be considered wholesome and safe for human consumption.

b. Food irradiated at doses exceeding 100 krad will be subject to toxicological testing consisting of a battery of four short-term mutagenicity tests and two 90–day feeding studies (one rodent. one nonrodent mammalian species).

c. A food class comprising no more than 0.01 percent of the daily diet and irradiated at doses of 5 megarads (Mrad) or less will be considered safe for human consumption without toxicological testing.

The work of the Committee did not include a complete evaluation of existing toxicologic data. The Committee focused on how the safety of irradiated foods can be scientifically evaluated. applying scientific principles. and not on whether any irradiated food has been demonstrated to be safe. Hence. these recommendations were based on: (1) projected levels of human exposure. (2) qualitative and quantitative estimates of radiolytic products and how these compare with common food constituents in the human diet. and (3) state-of-the-art sensitivity of toxicological tests.

The agency has accepted the Committee's report on the safety evaluation of irradiated foods and will supplement this report with recent experimental data relevant to the safety of irradiated foods.

The agency is considering the following actions:

1. Proposal of a regulation on the Commissioner's initiative under section 409 and other provisions of the act permitting irradiation of any food at a dose not exceeding 100 krad. FDA is initially considering monitoring food irradiation at such a dose by a registration process. Alternatively. FDA is also considering requiring a limited petition that demonstrates the intended technical effect of the process but without the additional safety data that would ordinarily be required to support a food additive petition.

2. Publication of guidelines for the preparation of petitions seeking FDA approval for food irradiation at a dose exceeding 100 krad.

3. Adoption of a policy that a food class comprising only a minor portion of the daily diet and irradiated at a dose of 5 Mrad or less may be considered safe for human consumption based upon minimal biological testing.

FDA also will consider the report of the Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food in its evaluation. This international committee. sponsored by the Food and Agriculture Organization. International Atomic Energy Agency. and the World Health Organization. first met in 1976 to review and assess all data on the wholesomeness of irradiated foods and to identify specific uses of food irradiation where data were sufficient to conclude that the process could be used safely. The most recent meeting of this Committee in Geneva from October 27 to November 3. 1980. was held to review data accumulated worldwide since 1976 to establish the wholesomeness of irradiated foods. The Committee's proceedings will have a direct bearing on any Codex Alimentarius standards that are developed for irradiated foods and sent to member States for approval.

Request for Comments

FDA invites public comment on all aspects of the agency's proposed food irradiation policy. The agency is particularly interested in receiving substantive comments on the Bureau of Foods' Irradiated Food Committee report. pertinent data on the safety of irradiated foods. and suggestions for any necessary safeguards for the irradiation processing of food. These comments will aid FDA in considering its irradiated foods policy. The agency is also aware of the following issues which may have a bearing on its deliberation:

1. Whether there is need for specific good manufacturing practice regulations. including any necessary safeguards. for the irradiation processing of food.

2. Whether there is need for labeling of irradiated foods. The present regulations require the following labeling declarations: "Treated with ionizing radiation" or "Treated with electron radiation" on retail packages. and "Treated with ionizing radiation—do not irradiate again" or "Treated with electron radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments.

3. The environmental impact of foods processed by irradiation or of the process itself.

4. The economic impact of the proposed agency actions. including any specific good manufacturing practice regulations and any labeling requirements that may be adopted. The proposed changes in criteria for evaluating the safety of processing of food may impose a less costly burden on food processors while still assuring safety.

Any proposed regulation based on this advance notice would have beneficial economic impact on manufacturers. due to reduced testing requirements. FDA requests information and views on whether any such proposed regulation will be a "major rule" under the criteria in section 1(b) of Executive Order 12291. as well as information to enable the agency to determine whether to prepare an initial regulatory flexibility analysis as required by the Regulatory Flexibility Act (Pub. L. 96–354. 5 U.S.C. 603 and 604). FDA specifically requests information on the total number of businesses affected by the proposal. the number of small businesses affected by the proposal. and the effect (in quantitative terms. where feasible) on each firm. including any small business.

Interested persons may. on or before June 25. 1981. submit to the Dockets Management Branch (HFA–305). Food and Drug Administration. Rm. 4–62. 5600 Fishers Lane. Rockville. MD 20857. written comments regarding this advance notice of proposal. Four copies of any comments are to be submitted. except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m.. Monday through Friday.

Dated: March 23. 1981.

Mark Novitch,

Acting Commissioner of Food and Drugs.

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Dr. **Miller.** On April 16 FDA extended the comment period for an additional 30 days, to May 16, 1984, and the comment period is now closed. At this time the Agency has received well over 3,700 comments in response to this proposal. The only proposal we have ever made which received a greater number of comments was our proposal to deregulate saccharine.

After review and considering all of these comments we will, of course, develop a final rule for the irradiation of foods.

If you will bear with me for just another moment or two, Madam Chairperson, I was asked if I would comment among other things on the future of food irradiation. I do so in this regard, taking off my official hat and putting on my personal hat. It is difficult to be both advocate and evaluator at the same time.

It is important to understand at the outset that FDA's responsibility in the evaluational process is limited to the determination of the safety of the process at the proposed effective doses. As I have indicated, FDA believes that the process is safe at the levels we have proposed. The question of its commercial feasibility is, of course, beyond the scope of our official evaluation. Nonetheless, after some 20 years of research in the field of food irradiation, I clearly have some personal views on the subject.

I believe that the extent to which food irradiation will become a commercially practical process is difficult to predict at this time because of the complexity of the issues and the fact that there are many, many other factors, in addition to technical feasibility and safety issues, involved.

Let me restrict myself to just one in particular. Probably the most difficult question to deal with is the kind of technical neophobia, if you will, in which the public is inherently suspicious of new processes, particularly those based upon technologies in which they cannot differentiate between the technology when used for different purposes. Thus the public continues to confuse the problems and potential hazards associated with the use of radiation for weaponry or power generation with those that may be associated with its use for food irradiation. They simply do not understand at this point that the irradiation process does not and cannot produce a radioactive product, and that the use of isotopic sources of ionizing radiation for food irradiation does not generate nuclear waste. Moreover, they forget that radiation has been used for the sterilization of hospital supplies for certain kinds of patients for many years without any ill effects.

Thus it seems to me that the industry has a major education effort ahead to convince the public that food irradiation is a safe and potentially useful technique to expand and improve our food supply. If this is not done, then I do not believe that this technology will be fully exploited.

It is difficult sometimes, Madam Chairman, to be sheriff in a frontier town when enthusiasm runs high. FDA's role in this process has been to evaluate its safety and its effectiveness to the purposes to which it is set. We are the sheriff, and this is the job that is given to us by law. We have concluded that, at the levels which we have established in our proposals, the process is safe and effective. It is now, I believe, the turn of the industry and the private sector particularly to begin to exploit this technology and to proceed from what has been, up to now, a fundamentally small-scale commercial activity, to its use as an important component of our food processing chain.

The Government has an important role to play, but it cannot play it alone. It must play it in conjunction with the industry. FDA will continue to fulfill its responsibilities by evaluating the safety of the process, particularly at levels higher than those that have been approved thus far. We are in the middle of such an evaluation now and hope to complete this review sometime within the next several months.

That concludes my summary, Madam Chairperson, and clearly, if you or any of your colleagues have any questions we would be happy to respond.

[The prepared statement of Dr. Miller follows:]

STATEMENT BY SANDFORD A. MILLER, PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman:

I welcome this opportunity to discuss with the Subcommittee the activities of the Food and Drug Administration (FDA) in the area of food irradiation.

My testimony also attempts to address your list of questions as they relate to the mission of the Agency.

BACKGROUND

While the use of irradiation for preserving food was explored as early as 1936, food irradiation research in the United States started in earnest in the late 1940's. It was only a few years later, in the early 1950's that the U.S. Government became interested in this new processing method. At that time the U.S. Army conducted a feasibility study of irradiated food and, based on organoleptic and biological tests, concluded that food irradiation could provide a wholesome, good-tasting, economical, and shelf-stable product for field rations; reduce dependence on refrigeration; and greatly reduce food handling costs for the military.

There was also substantial civilian interest in this new technology. As part of President Eisenhower's "Atoms for Peace" program, the Atomic Energy Commission (AEC) had an early interest in food irradiation, especially at low-doses for insect control and shelf-life extension of fruits and vegetables as well as for control of microorganisms in food.

Considering the widespread interest in food irradiation, it was not surprising that FDA was interested almost from the start.

FDA's involvement in the nutritional and toxicological aspects of irradiated foods began in the early 1950's when in close cooperation with the military, the U.S. Department of Agriculture and interested parties in the private sector the Agency suggested wholesomeness testing measurement for these products.

EFFECTS OF FOOD IRRADIATION

Before discussing the regulatory action of FDA involving irradiated food, first, let us briefly review the technical effects of food irradiation. A table listing the technical effects of radiation on food is attached to my statement as Appendix A. To a significant degree the technical effect of radiation on foods is dependent on two principal factors:

— First, the effect of radiation is cumulative, and is directly proportional to the total dose.

— Second, the effects of radiation on materials are dependent on the complexity of the material.

For example, living material is affected more profoundly than inanimate material; multicell organisms are affected more readily than single cell organisms; growing organisms are affected more readily than dormant organisms. Thus, irradiation can affect sprouting of root crops at low doses (5-15 krads). Similarly, you can delay the ripening of fruits and vegetables because they are still "alive" and maturing.

Insects are affected at about 15-100 krads depending on their stage of development (egg, larvae, adult). At doses above 100 krads, microorganisms are significantly affected.

Finally, the dose required to produce a commercially sterile product (i.e., the dose required to produce a one trillion-fold reduction in pathogenic microorganisms) is about 2-6 Mrad, depending on the food. It is important to note that even at these sterilizing doses, enzymes and viruses are relatively unafffected.

SAFETY ISSUES

Many years of research on the irradiation process have shown that the proposed levels of irradiation are safe.

The fundamental health concern for foods treated with ionizing radiation have not changed for 40 years.

— First, there was the possibility of induced radioactivity;

— Second, there was concern for the possible long-term toxicological effects of the radiolytic products formed in foods as a consequence of this irradiation process; and

— Third, there was concern about the effects of irradiation on the microbial flora of the food and on the nutritional quality of the treated food.

Of these, the two concerns that received the most attention associated with the safety of irradiated foods involve the possibility of increased exposure of the consumer to radiation (i.e., induced radioactivity) and/or exposure to new chemicals (radiolytic byproducts) formed as byproducts of the irradiation process. What has developed in 40 years, however, is a body of scientific data sufficient to evaluate the safety of food irradiation that helps to address these longstanding concerns.

The first issue, the induction of radioactivity in food components, was investigated by the National Bureau of Standards and the National Academy of Sciences in the early 1960's. After extensive testing and development of several theoretical models, they concluded that an increase in radioactivity cannot be detected in food if the radiation source is Cobalt 60 (Co 60), Cesium 137 (Cs 137), or machines which produce radiation at appropriate energy levels. Thus, the concern that consumers will be exposed to additional radiation by the irradiated food is unfounded.

The second issue, the safety of radiolytic products, has required longer and more complex evaluation. We have known since the 1950's that a major problem with safety evaluation of irradiated foods has been the difficulty in establishing the identity, amount and toxicity of the radiolytic products formed in food by irradiation. In the beginning, attempts were made to assess these products for safety by using traditional animal feeding studies. This was thought to be the most pragmatic approach for establishing the safety of irradiated foods in the absence of more sensitive analytical methods. Increased understanding of the radiation chemistry of the potential residues associated with food irradiation allowed us to develop and apply appropriate criteria to evaluate the safety of foods irradiated under different conditions. In other words, with knowledge of the chemical changes occurring in irradiated foods, we can specify safe conditions of use by establishing the maximum doses of radiation permitted to be applied to the food. Thus, at the radiation doses FDA has proposed for treatment of foods, the irradiated food is virtually indistinguishable from the equivalent nonirradiated food, and the types and amounts of radiolytic products formed are such as to make the foods indistinguishable with respect to safety. I will discuss this approach in more detail in just a moment.

INTERNATIONAL INTEREST

In the 1960's, the potential use of this new food process aroused much international interest so that several organizations of the United Nations, (the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the International Atomic Energy Agency (IAEA)) formed committees of experts knowledgeable in many disciplines to review data and make recommendations regarding this new food processing method. The members' areas of expertise included food technology, packaging, biochemistry, microbiology, public health, pharmacology, toxicology and radiation technology.

The sponsoring organizations believed that the recommendations of a body of experts with such a breadth of skills could influence various countries to adopt a common approach to legislation and regulation for the commercial production and use of irradiated food. The recommendations of these meetings were published in a series of Joint Expert Committee reports on various aspects of food irradiation, including the technology of food irradiation, radiation chemistry, nutrition, microbiology and toxicology.

The latest report of the 1980 Joint Expert Committee meeting on the acceptability of irradiated food concluded the following:

- The irradiation of any food commodity up to an overall average dose of 10 kGy (1 megarad) presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required.
- The irradiation of food up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems. However, the Committee emphasized that attention should be given to the significance of any changes in relation to each particular irradiated food and to its role in the diet.
- The Committee considered that future research is needed in various areas to increase existing knowledge about the effects of irradiation

on food and to facilitate future evaluations. Some of the areas included:

- establishment of the technological and economic feasibility of conducting food irradiation on a larger scale and the suitability of irradiating a wider variety of foods;
- further wholesomeness studies of certain foods irradiated at higher doses; and
- a systematic collection and review of information on the effects of using radiation sterilized human diets.

FDA is still considering both the Committee recommendations and the supporting data. In addition, FDA has undertaken its own review and, as a result, recently issued a proposal to permit low doses of irradiation of food for certain purposes. I will say more about that in a moment.

Other countries are also considering the recommendations of the Joint Expert Committee as well as the soon to be published Codex General Standard for Irradiated Food derived from the reports of the Joint Expert Committee. At this time, more than twenty countries have regulations approving one or more uses of food irradiation for commercial or experimental purposes. Under Codex rules, member countries review and evaluate the proposed Codex standards with respect to their own individual food laws. These standards can be accepted without change, accepted with change, or not accepted.

Thus, at this time, the regulatory status of food irradiation in different countries is in flux, as each country reviews the Codex proposal example and decides how to best harmonize their food irradiation regulations. Therefore, we do not have a reliable, up-to-date accounting of the different regulatory requirements. Although still quite small, we believe the amount of food irradiation is growing.

REGULATORY STATUS

FDA's special involvement in food irradiation is mandated by the Food Additives Amendment of 1958, which specifically includes a source of radiation in the definition of a food additive. This legislation requires premarket approval before a source of radiation may be used to process food and states that a food is adulterated if it has been intentionally subjected to radiation unless a food additive regulation covers such use.

Thus, the statute requires FDA to evaluate the safety of irradiated foods and, if appropriate, issue regulations that establish safe conditions for irradiating food before any irradiation process may be used commercially.

The proposal FDA published in February 1984 was preceded by earlier actions concerning irradiation of food. A historical list of regulatory actions on food irradiation is attached as Appendix B. As you will notice, we have permitted the use of irradiation for the control of insect infestation of wheat and wheat products since 1963 and the use of irradiation of potatoes for sprout inhibition since 1964.

The first approved use of irradiation in the United States was for the radiation sterilization of canned bacon in 1963. However, this regulation was rescinded in 1968 because a later examination of the raw data for the animal feeding studies showed major deficiencies in the way some of the experiments were designed and conducted. Thus, because of experimental deficiencies FDA could no longer conclude that the irradiation of bacon (and ham) had been shown to be a safe process. On the other hand, FDA scientists could not conclude that processing by irradiation would produce unsafe food, and left the door open to further consideration on the basis of additional studies designed to answer the questions raised.

Many difficulties have been encountered in the development of appropriate criteria for determining whether irradiated foods are safe. The earlier premise that long-term animal feeding studies were always the most appropriate way to establish the safety of irradiated foods has been increasingly questioned.

Because of these concerns, in the fall of 1979, as the Director of the then Bureau of Foods (now Center for Food Safety and Applied Nutrition), I established the Bureau of Foods Irradiated Food Committee, consisting of six Agency scientists. The Committee was charged to review the Agency's practice for evaluating the safety of irradiated foods and to recommend criteria for safety evaluation according to the current state-of-the-art knowledge in toxicology, nutrition, and radiation chemistry.

The basic objective of this study was to develop criteria for assessing irradiated foods that would more rationally establish safety than traditional animal tests and yet assure safety to the same degree that is expected for other foods in the American food supply. The Committee reported to the Bureau Director in 1980 that further safety testing of foods irradiated below 1 kGy (100 krad) and of minor ingredients, such as spices, irradiated at doses up to 50 kGy (5 Mrad) would serve no useful purpose. The Committee also concluded that the type and amount of radiolytic products formed in foods irradiated below 1 kGy were such that the irradiated food was as safe as the nonirradiated food. Furthermore, there would be no significant difference in nutritional value under these conditions. Rationale of the Committee's conclusions are provided in more detail in the Bureau's 1980 report and the February 14, 1984 Federal Register proposal (copies submitted for the record).

The Agency published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register on March 27, 1981 (copy submitted for the record). That notice was based on the criteria for safety evaluation recommended by the Irradiated Food Committee and was the first step in the administrative process which was intended to establish new operating criteria for evaluating safety data for irradiated foods.

After a full analysis of all comments to this ANPR and following discussions with a wide variety of industry, university, and international scientists, FDA, on February 14, 1984, proposed a rule in the Federal Register to permit the use of irradiation for (1) sprout inhibition and shelf-life extension of fresh fruits and vegetables and for insect disinfestation of food at doses not to exceed 100 krad; and (2) for sterilization of spices at doses not to exceed 3 Megarad.

Except for spice sterilization, this proposal does not deal with the use of radiation for the control of microorganisms, such as bacteria, molds and yeast in foods, and it does not deal with parasite control in meats, such as trichina.

Although we believe that the safety of food irradiation below 1 kGy (100 krad) has been established, the Agency proposed to limit the use of food irradiation according to intended technical effect rather than simply by dose. This was done to aid enforcement of dose limits because there would be no reason to exceed the permitted dose. For example, over-treatment of fruits and vegetables may adversely affect their marketing qualities. Thus, exceeding the permitted dose would result in a substandard product. In effect, compliance occurs due to a self-limiting factor. We are aware that the permitted dose limitation also may be somewhat effective for other uses, such as decreasing the microbial burden in meat, fish, and poultry. However, we have not proposed these uses at this time because irradiating at such low doses would not be sufficiently effective for microbial control to be self-limiting. We are not yet totally satisfied that raising the permitted dose would pose no problems.

In addition, the Agency initially proposed in the 1981 ANPR that 50 kGy (5 Mrad) of irradiation would be considered safe for dried spices because they are used for seasoning agents and that total consumption of spices constitutes only a minor portion of the diet. However, after evaluating additional data, the Agency has limited the proposed maximum permitted radiation dose to 30 kGy (3 Mrad) in keeping with our policy to set tolerances no higher than is reasonably required for the intended use. Published reports indicate that doses of 15 to 25 kGy are effective for spice sterilization and that consideration for organoleptic qualities of spices may result in an acceptable average dose of about 20 kGy.

The proposal provided for a 60-day comment period which closed on April 16, 1984. FDA extended the comment period 30 days to May 16, in response to several requests. Over 3,900 comments have been received. FDA is currently cataloging the comments to create a more systematic index for evaluation and to assure that all issues are adequately addressed in the record. The number of comments submitted for consideration and the number of issues raised are substantial.

The comments have come from consumers, consumer groups, the radiation industry, labor, the food industry, trade associations, law firms, State and local governments and agencies, academic and Government scientists, and Federal agencies. Comments received essentially addressed all issues discussed in the proposal: safety of radiolytic products; the need for reliable long-term feeding studies, nutrition; growth of microorganisms or toxin production by microorganisms not killed by the process; retail labeling; enforcement of dose limits; training of operators; and the transport, storage, and disposal of nuclear materials.

FUTURE RESEARCH

The continuing issues in food irradiation center around what is meant by "safe" and what is "reasonable certainty of no harm." All foods are likely to contain small amounts of toxic substances that are present naturally. Processing will always cause unknown changes. Absolute certainty of safety is no more possible today than when the food additives amendment was passed establishing "reasonable certainty" as the standard of safety.

As stated earlier, the Irradiated Food Committee concluded that there is reasonalbe certainty, that at the proposed dose levels, the irradiated food is as safe as the nonirradiated food. In addition the Committee developed and recommended criteria for assessing the safety of irradiated food at other doses.

In a concurrent review of some 400 toxicological studies, our reviewers have concluded that many of the animal feeding studies conducted during the past 30 years with irradiated food are not of acceptable quality by current toxicological standards. Although, they may not meet current requirements, the studies do not appear to show adverse toxicological effects attributable to irradiated foods.

Recently, USDA submitted to FDA some 50,000 pages of data on radiation sterilized chicken meat. Some comments submitted to the FDA opposing food irradiation have cited these data as demonstrating adverse effects. FDA is currently reviewing these data. It is important to note that these data do not impact on our current proposal which is designed to regulate foods irradiated at much lower doses.

There are a number of issues that can be raised questioning the safety of irradiated food. Although we have no reason to say that food irradiated under any condition is unsafe, we believe that the uncertainties remaining are of no importance under the conditions of our proposed regulation.

We also recognize, however, that as irradiation doses increase and as the amount and types of irradiated food increase, important questions arise that need to be answered prior to approving new uses of food irradiation, particularly at higher doses. The report of the Irradiated Food Commitee suggests that additional biological tests, and more importantly, better knowledge of chemistry at the high dose levels will be useful in evaluating the safety of such foods.

ALTERNATIVE TO EDB AND OTHER PESTICIDES

Whether food irradiation will be a commercially practical alternative to the use of EDB and other pesticides in the fumigation of food is difficult to predict at this time because of the complexity of the issue. Many other factors in addition to technical feasibility are involved. It is important to understand that FDA's responsibility in the evaluation process is limited to the determination of the safety of the process at the proposed effective doses. As I have indicated, FDA believes that the process is safe at the proposed levels and can be effective for insect disinfestation of food. The question of its commercial feasibility is beyond the scope of FDA's official evaluations. Nevertheless, after some 20 years in research in the field of food irradiation, I do have some personal views on the subject.

It is true, I believe, that food irradiation does have the potential to replace to a significant extent the use of chemical fumigants in the treatment of foods. Certainly from a safety point of view, this process represents a very low level of hazard—one considerably less than that associated with the use of most chemical substances for this purpose. It is also true that the fundamental concepts required to use irradiation to reduce the insect burden are already available. Indeed, experimental irradiation devices have already been used for this purpose. Nevertheless, there are several important problems that will have to be resolved before food irradiation can become a significant commercial reality. For example, research must be done on each food to determine the dose at which effective disinfestation will occur and yet not adversely affect the marketability of the product. The capital costs of the facilities, as well as the continued operating costs, will also have to be evaluated very carefully to determine the long-term viability of using radiation for this activity. Among the more difficult problems is the decision of whether the primary radiation facility will be isotope-based or machine-based. To a large extent, this decision will be based upon the particular industry involved. For the citrus industry, for example, it may be that permanent large scale centralized irradiation facilities using isotopes as a source of radiation may be more reasonable and more economical than the use of machine-derived energy. On the other hand, the nature of the grain and flour business would suggest that the smaller, more portable, machines might be required. In this case, the only feasible approach would be the development of irradiation devices using machine-derived energy. Such devices are theoretically possible, and, indeed, have been developed for other purposes such as checking the integrity of struts on bridges and determining flaws in metal that is to be used for construction purposes.

It is obvious, I believe, that these are basically technical and economic problems and, therefore, are subject to rigorous objective analysis. I am quite certain that if the desire was there, the problems could easily be solved because the basic science is already in place. There are, I believe, much more difficult questions to deal with. In the United States a kind of "technical neophobia" exists. The public is inherently suspicious of new processes, particularly when the same technology is used for different purposes. Thus, many continue to confuse the problems and potential hazards associated with the use of irradiation for weaponry or for power generation and believe that those same hazards may be associated with its use for food irradiation. Many do not know that irradiation has been used for many years in the sterilization of hospital supplies with no indication of any harmful effect. Many also do not understand, at this point, that the irradiation process does not produce a radioactive product and, more importantly, that even in the use of isotopic sources of ionizing radiation, there is no generation of nuclear wastes. Indeed, it is conceivable under some circumstances that the food irradiators will utilize some of the wastes generated by nuclear power plants. It is clear, I think, that industry ought to consider initiating some kind of public education program to demonstrate to the consumer that this is a safe and potentially valuable process. One has to be careful, however, that the process and its potential is not oversold. Food irradiation is a very useful technology but only one of several that are important if we are to maintain and, indeed, improve our food supply. We have been fortunate in the United States that we have not only been blessed with an abundance but with a technological base that has allowed us to continue to expand our food supply as our population has required.

FDA's role in this process has been to evaluate its safety and its effectiveness for its intended uses. We have concluded after some 40 years of investigation that, at the levels which we have established in our proposals, the process is safe and effective. It is now, I believe, the turn of industry and the private sector to begin to exploit this technology and to proceed from what has been, up to now, a fundamentally small scale commercial activity, at best, to its use as an important component of our food processing chain. FDA will continue to fulfill its responsibility by evaluating the safety of the process, particularly at levels higher than those which have been approved thus far.

Some uses do require higher levels of irradiation in order to accomplish their purpose. We are in the middle of such an evaluation now and hope that sometime within the next several months to complete this review.

This concludes my statement, Mr. Chairman. If you or your colleagues have any questions, we would be glad to respond to them.

APPENDIX A

TECHNICAL EFFECTS ON FOOD

A. Sterilization*	2,000 to 6,000 krads (2 to 6 Mrads)
B. Texture Modification	700 to 1,000 krads
C. Microbial Control (bacteria, fungi)	100 to 1,000 krads
D. Insect Control	Less than 100 krads
E. Maturation Inhibition	Less than 100 krads
F. Parasite Control	Less than 100 krads

NOTE: * Irradiation at practical doses will not affect viruses or enzymes.

Appendix B

IRRADIATED FOODS

History of Actions

- February 1963: FDA approved gamma radiation for the radiation preservation of canned bacon.
- August 1963: FDA approved gamma radiation for control of insect infestation of wheat and wheat products.
- August 1963: FDA approved electron beam radiation for the radiation preservation of canned bacon.
- October 1964: FDA approved gamma radiation for sprout inhibition of white potatoes.
- December 1964: FDA approved X-radiation for the radiation preservation of canned bacon.
- July 1966: FDA approved electron beam radiation for the control of insect infestation of wheat and wheat products.
- July 1966: FDA approved labeling requirements for food treated by radiation.
- October 1968: FDA rescinds the bacon regulations.
- September 10, 1979: Director, Bureau of Foods establishes the Irradiated Food Committee to provide a total reassessment of all relevant issues applicable to irradiated foods.
- March 27, 1981: Advance Notice of Proposed Procedures for the Regulation of Irradiated Foods for Human Consumption (ANPR) published in the Federal Register.
- Autumn, 1981: FDA offered the opportunity for use of irradiation for insect disinfestation during the California Medfly situation based on certain conditions. However, no firm furnished evidence of meeting these conditions.
- July 5, 1983: FDA approved gamma radiation for microbial decontamination of a specific list of spices and vegetable seasonings.
- Feburary 14, 1984: Proposed rule published in the Federal Register. FDA proposes a regulation for sprout inhibition and shelf-life extension of fresh fruits and vegetables, for insect disinfestation of food, and for sterilization of spices.
- June 19, 1984: FDA amended the food additive regulation to provide for the safe use of a source of gamma radiation to control insect infestation in garlic powder, onion powder, and dried spices.

Mrs. LLOYD. Thank you very much, Dr. Miller.

Dr. Kinney, would you proceed with your testimony?

STATEMENT OF DR. TERRY B. KINNEY, ADMINISTRATOR AGRICULTURE RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY WILLIAM HELMS, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, MILTON OUYE AND RICHARD PARRY, AGRICULTURAL RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Dr. KINNEY. Thank you very much. Madam Chairman and members of the subcommittee, I appreciate the opportunity to participate in these hearings today.

I have with me Mr. William Helms from the Animal and Plant Health Inspection Service in the Department, and Doctors Milton Ouye and Richard Parry from the Agricultural Research Service.

I will summarize my statement in part and submit the total for the record.

The Agricultural Research Service has conducted research on food irradiation for more than 30 years. For the purposes of discussion today, I'd like to describe our program in three parts. First, lower irradiation doses up to 100 kilorads for insect disinfestation and plant growth inhibition; second, irradiation doses between 100 kilorads and 1 megarad for the control of microorganisms for pasteurization; and third, irradiation doses at high levels above 1 megarad to sterilize food.

For low dose irradiation our research effort is on development of quarantine treatment for insects as an alternative to chemical fumigants, and trichina control in pork. Use of radiation to disinfest insects from wheat and flour as well as inhibition of potato sprouting were approved by the U.S. Food and Drug Administration in the 1960's, as pointed out by Dr. Miller.

Research on control of the Mediterranean, oriental, and melon fruit flies found in Hawaiian papaya was completed several years ago, the data were analyzed, and it appears that a dosage of 15 kilorads will provide quarantine security. A successful commercial fruit irradiator must carefully monitor the dosage to achieve insect quarantine security and also avoid reducing quality of the produce.

Planning is now in progress for installation of a cesium agricultural commodities irradiator at our Miami Subtropical Horticultural Products Laboratory. This program will be carried out in cooperation with the Department of Energy, as my colleague from that agency pointed out.

No formal approval or commercial use will be made until FDA makes a final determination on the low dose irradiation regulation. Other insect pests and commodities that are being studied include the Caribbean fruit fly and and Mexican fruit fly in mangoes and grapefruit, and the codling moth in apples and cherries. Work will also be initiated on codling moth in walnuts. Research is being conducted to compare the dosage necessary to kill insects as compared to the dosage necessary to prevent production of offspring from survivors of a treatment.

Low doses of irradiation can also eliminate trichina parasites from pork and pork products. The ARS research, in cooperation with DOE and other organizations, has demonstrated that 10 to 20 kilorads treatment of pork will render this organism non-infectious. We are continuing to evaluate low irradiation doses on pork to control other organisms of food safety concern.

Medium dosage irradiation to reduce bacterial contamination can be achieved between 100 kilorads and 1 megarad. Studies are underway to determine shelf-life extension of meat and poultry, reduction of microbial spoilage, and reduction or elimination of food poisoning bacteria. Research is also continuing on the irradiation effect on the subcellular level of foods, as well as changes in lipid composition which may occur. This method shows promise as an alternative to nitrite for preservation of meat.

Sterilization of food by irradiation has been investigated for many years by the Department of the Army and USDA. In 1980, the Army transferred to us their program activities related to irradiation processing of meats. This consisted of data generated from their completed work, funds to complete certain food toxicology studies already in progress, four professionals, and specialized equipment.

The animal toxicology studies and summaries of information relating to the food chemistry, microbiology, and processing were completed earlier this year. The data package relating to wholesomeness studies of precooked chicken exposed to 5.9 megarad doses of ionizing irradiation sufficient to achieve commercial sterility was delivered to FDA on March 30 of this year. The Food and Drug Administration has indicated that they would not initiate rulemaking on this issue, but they would review the data to determine whether there is sufficient information to prescribe safe use of irradiation to sterilize chicken.

Our future research in the Department will be to concentrate on low-dose irradiation studies for quarantine treatment and on the moderate dosage to determine relative susceptibility of bacteria to irradiation. Further research on sterilization doses is not planned at this time.

The proper role for Government in the development of a new technology is to assure that proper safeguards have been identified for consumer protection and product quality. The USDA will continue to conduct research and provide technical information to the industry and consumers that can lead to implementation of irradiation processing of food by the industry.

Madam Chairwoman, this concludes my statement. I would be glad to respond to any questions. Thank you.

[The prepared statement of Dr. Kinney follows:]

STATEMENT OF DR. TERRY B. KINNEY, JR., ADMINISTRATOR, AGRICULTURAL RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Madam Chair and Members of the Subcommittee, I appreciate the opportunity to participate in these hearings.

The Agriculture Research Service (ARS) has conducted research on food irradiation for more than 30 years. For the purpose of our discussion today, I would like to discribe our program in three parts. First, lower irradiation doses up to 100 kilorads for insect disinfestation and plant growth inhibition. Second, irradiation doses between 100 kilorads and 1 megarad (medium dosage) for control of microorganisms for pasteurization. And third, irradiation doses at high levels above 1 megarad to sterilize food.

For low dose irradiation our research effort is on development of quarantine treatment for insects as an alternative to chemical fumigants, and trichina control in pork. Use of radiation to disinfest insects from wheat and flour as well as inhibition of potato sprouting were approved by the U.S. Food and Drug Administration (FDA) in the 1960's. Research on control of the mediterranean, oriental, and melon fruit flies found in Hawaiian papaya was completed several years ago, the data analyzed, and it appears that a dosage of 15 kilorads will provide quarantine security. A successful commercial fruit irradiator must carefully monitor the dosage to achieve insect quarantine security and also avoid reducing quality of the produce.

Planning is now in progess for installation of a cesium agricultural commodities irradiator at our Miami Subtropical Horticultural Products Laboratory. This program will be carried out in cooperation with the Department of Energy (DOE) and Agency for International Development (AID). ARS will provide space for the unit which will be used in our work to develop quarantine treatments for Caribbean fruit flies in Florida citrus over a two year period. AID is considering using this irradiator as a training site for Caribbean Basin countries scientists and specialists. Until this special unit and others now under consideration is constructed, we will continue to use our existing irradiation facilities to evaluate irradiation as one alternative to fumigants for commodity treatment.

No formal approval or commercial use will be made until FDA makes a final determination on the low dose irradiation regulation. Other insect pests and commodities that are being studied include the Caribbean fruit fly and Mexican fruit fly in mangoes and grapefruit, and the codling moth in apples and cherries. Work will also be initiated on codling moth in walnuts. Research is being conducted to compare the dosage necessary to kill insects as compared to the dosage necessary to prevent production of offspring from survivors of a treatment.

Low doses of irradiation can also eliminate trichina parsites from pork and pork products. ARS research in cooperation with DOE and other organizations has demonstrated that 10 to 20 kilorads treatment of pork will render this organism noninfectious. We are continuing to evaluate low irradiation doses on pork to control other organisms of food safety concern.

Medium dosage irradiation to reduce bacterial contamination can be achieved between 100 kilorads and 1 megarad. Studies are underway to determine shelf-life extension of meat and poultry, reduction of microbial spoilage, and reduction or elimination of food poisoning bacteria. Research is also continuing on the irradiation effect on the subcellular level of foods, as well as changes in lipid composition which may occur. This method shows promise as an alternative to nitrite for preservation of meat.

Sterilization of food by irradition has been investigated for many years by the Department of Army and USDA. In 1980, the Army transferred to us their program activities related to irradiation processing of meats. This consisted of data generated from their completed work, funds to complete certain food toxicology studies already in progress, four professionals, and specialized equipment.

The animal toxicology studies and summaries of information relating to the food chemistry, microbiology and processing were completed earlier this year. The data package relating to wholesomeness studies of precooked chicken exposed to 5.9 megarad doses of ionizing irradiation sufficient to achieve commercial sterility was delivered to FDA on March 30, 1984. The Food and Drug Administration has indicated that they would not initiate rulemaking on this issue but they would review the data to determine whether there is sufficent information to prescribe safe use of irradiation to sterilize chicken.

Our future research will be to concentrate on low dose irradiation studies for quarantine treatment and on the moderate dosage to determine relative susceptibility of bacteria to irradiation. Further research on sterilization doses is not planned at this time.

Commercial irradiation processing of food will require more precise control of dosage given to the commodity than treatments for non-food products. Irradiation for sterilization of medical supplies or polymerization requires only minimum exposure criteria be met. On the other hand, food processing will require continous monitoring to asssure that carefully defined limits of minimum and maximum exposure are maintained at all times. A maximum exposure dosage level for food is needed to assure regulatory compliance as well as avoiding damage which has observed with some commodities such as grapefruit.

Food irradiation by U.S. industry has not been as rapidly adopted as in some foreign countries. Speices are the only commodity being commercially treated with irradiation in the United States. FDA approved irradiation treatment at 20-50 kilorads for insect disinfestation in wheat and wheat flour in the 1960's, but it has not been implemented by the U.S. grain industry. The lack of implementation of this technology for wheat indicates that other commodities may face similar impediments to irradiation, especially when cheaper alternatives may be available.

The proper role for government in the development of a new technology is to assure that proper safeguards have been identified for consumer protection and product quality. The USDA will continue to conduct research and provide technical information to industry and consumers that can lead to implementation of irradiation processing of food by industry.

Madam Chair, this concludes my prepared statement. I will be pleased to respond to any questions you may have.

Mrs. LLOYD. Thank you very much.

I think right now that we do have a live quorum call, so we will stand in recess while the Chair votes. I will be back shortly. Thank you.

[Short recess taken.]

Mrs. LLOYD. We will resume our hearings.

Dr. Miller, in general can you discuss a little bit further the nature of the comments that have been received by your Agency in response to the proposed rules that were published in the Federal Register? I mean, not lengthy ones, but just generalities?

Dr. MILLER. I can make some general statements, but it's hard to make specific statements or draw any conclusions because they are in the middle of the rulemaking at this time. But I think that there are probably three or four different general kinds of comments that were made.

There were a substantial number of comments that came from consumers who simply did not, and do not, understand the nature of the process, nor do they understand what the basic safety issues really are concerning things like radioactive food products glowing in the dark, and things of that kind. And it's a very serious problem and one that we're going to have to deal with, as I mentioned in my testimony.

The second group of comments, by far the largest number, had to do with the demand on the part of many people that these products be labeled. This is a very complex issue, very difficult one. There are legal constraints and considerations as well as practical ones in this regard, and this is going to be a very difficult one for us to resolve.

Mrs. LLOYD. The labeling one is one that came to my mind as I was listening to your testimony. For instance, I just don't really know how we're going to label this apple.

Dr. MILLER. Well, there are different levels of labeling, and——

Mrs. LLOYD. That's not my question; this is a question that would be raised.

Dr. MILLER. Of course, and that's one of the problems. It would be very simple, if it was necessary, for the Agency to say that the store using irradiated apples will have to put a sign up saying, "We use irradiated apples." But the enforcement of that becomes extremely difficult. That's what I mean by saying that that's an extremely difficult issue. There's a strong public feeling that, irrespective of their views on this subject, they at least have the right to know that it has been irradiated, to make their choice. But then, as I say, there are the practical, legal, and enforcement concerns for which we have to very seriously consider what our role will be. We've concluded nothing because we're in the middle of reviewing.

Mrs. Lloyd. If you have further comments along this line, we would appreciate hearing from you.

Dr. Miller. Yes. Certainly.

Mrs. Lloyd. And please give my regards to Ms. Heckler.

Dr. Miller. I shall. Thank you.

Mrs. Lloyd. Mr. Cunningham, has the NRC licensed the use of cesium-137 in irradiation facilities of any kind, and are there any licensing applications being considered?

Mr. Cunningham. Madam Chairman, we have licensed cesium in small irradiators. These are usually ones used in universities containing, oh, maybe up to 1,000 curies of cesium or a few thousand curies; very much smaller than the commercial irradiators. We have received one application at the NRC to use cesium in the capsules being supplied by DOE, and I understand that an agreement State has also received one application. We will assist that State in reviewing the application if requested.

Mrs. Lloyd. How long do you think it will take to process an application?

Mr. Cunningham. The processing of the application itself doesn't take very long. It can be done in weeks or months; it depends on the quality of the application and the questions that may be raised. There are some basic questions about the cesium capsule itself related to capsule performance. We have held discussions with DOE; they are doing some experimental work which we anticipate will give us the performance data we need to act on licenses from these two applicants and for any others that may be received. DOE's schedule for this, in my last meeting with them, was information on corrosion rates in about 2 months' time. They have already supplied some, but they have a program that—I think it will be completed in about 2 months. The thermal recycling work that they are doing will be completed in about 6 months. These are for irradiators that have wet storage, dry irradiation. There is a thermal recycle; these capsules have a relatively high heat load, and there's a question——

Mrs. Lloyd. But basically speaking, it's not an overriding concern?

Mr. Cunningham. No; it is not an overriding concern. But these capsules with cesium salt do raise questions that aren't prevalent in the cobalt-60 where you have them in metallic form. We think we will get answers we need, but we have to have the data to——

Mrs. Lloyd. But the timeframe would not be over a timespan of multiple years that would increase the process?

Mr. Cunningham. That is correct. Hopefully, at the end of 6 months, we will be ready to take licensing action on the wet storage/dry irradiation, which is the one we received an application for; and I understand the one in Colorado was dry storage/dry irradiation. That's the agreement State that received the other application.

Mrs. Lloyd. Well, as I'm sure you know, Congressman Morrison's bill which I'm a cosponsor of, proposes that we lease cesium from DOE rather than purchase. Does this require any unusual regulatory concerns?

Mr. CUNNINGHAM. Not that I am aware of. As a matter of fact, it might help——

Mrs. LLOYD. That's what I'm saying. Would it help, since it would be returned?

Mr. CUNNINGHAM. Yes, I think so, because these are large quantities of materials; and in the licensing process we have to see a way for disposal of these sources eventually. Right now in the commercial sector the prospect isn't very good. If they're returned to DOE to be incorporated in their Defense Waste Program, it makes it much easier for licensing, I think.

Mrs. LLOYD. Thank you very much.

Dr. Kinney, I think we're going to have to really have a very large education program on food irradiation if we're going to receive the benefits. Do you have any public education programs that are now underway, or some that you're planning, to project the wholesomeness of irradiated food, the advantages of irradiated food; or do you think this is a proper activity for the Department of Agriculture?

Dr. KINNEY. Madam Chair, I think it's a proper activity for the Department of Agriculture in part through our Food and Nutrition Service, and obviously through our Extension Service. But I feel until the status of food irradiation is clarified it might be counterproductive to initiate an educational program now.

I also feel strongly that the principal role in terms of education should be played by industry. I think it traditionally has been played by industry in most new areas of food processing and so forth. But the Department will cooperate in——

Mrs. LLOYD. We Members of Congress, we get lists of publications from USDA, a little checklist on what we want to send our consumers, and we've certainly taken advantage of it and they have been well received by our consumers. Now, I don't see that there's a great deal of difference in that type of consumer education and in what you would need to be played on the subject of food irradiation, so I respectfully disagree with you on that issue; this is a role that you can play.

Dr. KINNEY. Yes. But what I'm saying is that I think all Federal agencies that have a role in either doing the research or the regulatory aspects must participate, but I also feel that industry must play a major role. We're talking about a very extensive and high-cost program if we're going to educate the public.

Through the Extension Service and the Food and Nutrition Service we can play a key role, but we can play only part of the role.

Mrs. LLOYD. Well, really, now from your perspective just how much is food irradiation worth to the consumer?

Dr. KINNEY. It depends about whether you talk about dollars and cents or health—exactly what you're talking about. I would say that right now, food irradiation is a potential technology that can be used to fill a role that may not be filled by some other things, such as EDB, in the near future. But it's only one; it's one of a number of technologies that must be brought to bear on providing safe and efficacious food.

Mrs. LLOYD. Well, you do have very fine testimony and I appreciate all three of you gentlemen being here today. Thank you very much and I look forward to hearing from you again. Thank you very much.

Our next panel is Dr. Jacek Sivinski, who is Director of Radiation Technology Programs for CH2M Hill; Dr. Garth Tingey, who is Senior Research Scientist at Battelle Pacific Northwest Laboratory. Welcome, gentlemen, to our hearing this morning. We look forward to your testimony.

Dr. Sivinski, you may proceed. You may summarize, if you wish; your entire testimony will be made a part of the record.

STATEMENT OF DR. JACEK SIVINSKI, DIRECTOR, RADIATION TECHNOLOGY PROGRAMS, CH2M HILL, INC.

Dr. **Sivinski**. Thank you very much, Madam Chairman. I am pleased to appear as a witness in this important hearing on the status of the technical infrastructure required to support food irradiation in the United States.

The current activities in the By-products Utilization Program, or the BUP, have been documented in Dr. Gilbert's testimony and I will not review them. I wish to state, however, that being a part of the program for the last 15 years is personally very satisfying. I am also pleased that by guessing correctly and hanging tough over the last 5 years we in the By-products Utilization Program are in a good position to deal with such pressing needs as EDB replacement and a decrease in pesticide and preservative residues.

One cannot mount the outstanding program described by Dr. Gilbert in 3 months, or even in 3 years. Had we given in to heavy pressures exerted by many quarters inside Government itself and in some of its laboratories to "dump the program" and get on with "something more important," the United States would be in a much poorer position to find reasonable and timely solutions to our current needs.

I will later address how important the initial nurturing by this committee was in that program.

Irradiation of nonfood items has led the technology considerably, and it has grown to a degree of maturity since the development of the Atoms for Peace Program initiated by President Eisenhower in 1953. Numerous sectors now use irradiation as a common technology. One of the most rapidly growing at this time is the medical products industry; currently, with the irradiators on the design boards now, 30 to 40 percent of sterile medical product will have been treated with irradiation to protect the public from exposure to the gaseous sterilant ethylene oxide, which is also on the Rebuttal Presumption Against Registration list by the EPA.

The growth of that particular industry has developed into a problem where we're going to run into a very high shortage of isotope problem in the very near future. A lot of the people feel that by the year 2000, certainly 90 percent of the medical products will have been sterilized by irradiation, and a more plentiful supply of gamma-producing isotopes will help.

One of the items to be addressed was the usage of machine-generated radiation, and that has grown significantly. Irradiation now is used to polymerize numerous kinds of insulation in wiring and cabling, initial setting of green rubber before being placed into tire molds, deposition and bonding of paper coatings, production of clear plastic wrap for meat and other products, sterilization of empty flexible cartons for asceptic packaging of foods and drinks and many other uses directly or indirectly impacting hundreds of billions of dollars worth of products. These activities go on everywhere worldwide and they are certainly growing.

There are some differences, however, between irradiation technology for these nonfood items and food irradiation. These differences preclude simple technology transfer to food. They include such items as significantly different technical effects desired in the irradiated product. In the medical product you have a larger margin for maximum/minimum ratios and so on; you are only held back in terms of physical properties such as strength, flexibility, brittleness, color, undesirable chemical changes, and so on.

Food, however, receives much closer scrutiny and a higher degree of concern because it is ingested on a recurring and long-term basis. I don't think I'll address much more of the stuff that is in the testimony about radiolytic products, but again, I think it is fair to say that more is known about food irradiation than any other technology that has ever been done with other kinds of food processes in the United States.

We have other differences which lie in such areas as seasonality of foodstuffs, which give us a problem; crops ripen at certain times, and you have gluts of material to be processed at that time and very little at other times of the year. The way material is packaged—it comes in pallet loads and frequently is very dense; the tonnages and throughputs will be many orders of magnitude greater than most nonfood products, and so on.

So these differences are the subject of study and design interest by that part of the commercial sector that sees great opportunity in food irradiation technology. It must be stated, however, there is still significant work to be done in evaluation of technical effects, such as efficacy in disinfestation, shelf-life extension, delay of ripening, onset of senescence, and so on.

On the other hand, I can assure you that the U.S. Department of Energy By-products Utilization Program and progress in food irradiation has drawn the highest praise and envy in the rest of the world—in Europe, Central and South America, Bangladesh, Thailand, India, the Philippines, and a number of other countries that I've been working with on food irradiation. And I'm working on it because they need it even more than we do, in Third World countries.

Many countries in Europe have been using it for a long period of time, and I think that has been rather well addressed so I will not go into it any further.

I would say that international trade in irradiated food products will be facilitated to the degree that the nations around the world accept the Codex Alimentarius Commission's recently approved food irradiation regulations and code of practice. This was done, Madam Chairman, last July in Rome and is at the final step; all it requires now is acceptance by the various countries of the one megarad absorbed dose as being unconditionally wholesome for human consumption. Many countries, including Canada, are in the process of accepting this one megarad dose; Bangladesh, for instance, has already accepted the complete Codex package some months ago without reservation. The current U.S. approach of creeping up to the Codex standard 100 kilorads at a time may put us at an economic disadvantage in terms of balance of trade for quite some period of time.

The problems of public acceptance I will not address, although they are in there. I will say that another major obstacle to program development is the lack of focus in the Federal Government itself on the technology. Some bits and pieces are being done by various departments and agencies, but lack of real commitment resulting in a lack of sponsorship, leading to a lack of funding, which then keeps good people away from the program is, in itself, a self-fulfilling prophecy of failure. Congressman Morrison's bill will provide the focus and integrate the activities by placing the responsibility in a Food Irradiation Commission. I think it's terribly important that everyone join me in hoping that that group will be so wisely constituted that they will have little trouble earning the cooperation of the various Federal departments and agencies supporting the work.

We have hit the ground running with a 3-year head start and are well on our way, and this is due to the responsiveness of the Armed Services and Appropriations Committee.

The agricultural and food industries need alternatives to some problem pesticides and preservatives. To say this, however, is not to give a blanket indictment to chemicals. Nothing could be more thoughtless since we would do badly without fertilizers, pesticides, and preservatives. But where problems do exist, irradiation may hold significant promise. It is not a panacea but should be considered as another tool which, when useful, might very well be the option of choice. I think many of them have been mentioned; the incentives, under certain conditions, are lower cost, better products, longer shelf life, less waste, increased food supply, better food nutrition, lower energy requirements, and so on—these are significant.

The machine-generated irradiation industry has not been addressed very much yet, and I think we should make the comment that in the United States and abroad they are very interested in their future role in the food irradiation arena. They attend the meetings, ask good questions, and many feel their time has come. I also believe they will have an important role in the total irradiation technology activities. They will be involved directly in food irradiation with high—8 to 10 MeV—electron beams, and indirectly by assuming a larger role in medical products irradiation where they will free up isotopes needed for the growth of the food irradiation industry.

In other words, we're going to have to learn how to use our resources more wisely and correctly for the intended use.

In closing, I must say that it is heartening to note the renewed interests of the Committee on Science and Technology in this program. I have been involved in isotope utilization-related activities since 1972, and it was this committee which originally nurtured the program through its infancy and helped get it off the ground. Other interests intervened, however, and as the needed support waned, the Armed Services Committee took on the role of moving programmatic objectives forward to the present status described by Dr. Gilbert. Their objectives of utilization of defense-related by-products have essentially been accomplished, and this program is ready for its "rites of passage." In the U.S. Department of Energy for technology development and commercialization oversight, to the U.S. Department of Agriculture for needed research support and implementation, to agencies such as the U.S. Agency for International Development where the technology is a powerful tool for the problems of worldwide food hunger, and to the U.S. Department of Commerce, where the export potential of U.S. technology, equipment, and commodities needs someone's undivided attention.

This, Madam Chairman, concludes my summary.

[The prepared statement of Dr. Sivinski follows:]

Testimony of
Jacek S. Sivinski
CH2M HILL, INC.

Madam Chairman, Members of the Committee, I am pleased to appear as a witness in this important hearing on the status of the technical infrastructure required to support food irradiation in the United States.

Current activities in the Byproducts Utilization Program (BUP) have been documented in Dr. Gilbert's testimony and I will not review them again. I wish to state however that being a part of the program is personally very satisfying. I am also pleased that by guessing correctly and "hanging tough" over the last 5 years we in the BUP are in a good position to deal with such pressing needs as EDB replacement and a decrease in pesticide and preservative residues. One cannot mount the outstanding program described by Dr. Gilbert in 3 months or even 3 years. Had we given in to the heavy pressures exerted by many quarters inside government itself, and in some of its laboratories to "dump the program" and get on with "something more important", the United States would be in a much poorer position to find reasonable and timely solutions to our current needs. That "something more important" was to bury those same so called "nuclear wastes" now so vital to food irradiation and which are in such short supply. This is not to say however that the Byproducts Utilization Program was singular in the field of irradiation technology, other non-food commercial activities were being developed at the same time in other sectors.

Irradiation of non-food items has grown into some degree of maturity since the technology began its development in earnest under the "Atoms for Peace" program initiated by President Eisenhower in 1953. Numerous sectors now use irradiation as common technology. One of the most rapidly growing at this time is the medical products industry. Currently 30 to 40 percent of sterile medical product has been treated with irradiation to protect the public from exposure to the gaseous sterilant ethylene oxide (ETO). The sterilant ETO is on the U.S. Environmental Protection Agency Rebuttal Presumption Against Registration (RPAR) list and OSHA has recently prescribed a fifty-fold decrease in facility operator exposure. The future of many ETO operations is economically bleak and a significant shift to radiation is taking place. This has resulted in a situation where current and past. It has been shown at doses below one megarad to be more benign than broiling, baking, roasting, frying, etc. Because of the above-mentioned concerns however, controls must be tight since regulatory tolerances will be tight.

Other differences lie in such areas as seasonality of many foodstuffs, leading to economic cost escalation if the facility cannot be kept on-line the maximum amount of time during the year. The doses may also vary considerably between irradiation of various agricultural commodities since the technical effects desired may be different. The susceptability to damage (phytoxicity) or flavor, taste, odor or mouthfeel change (organoleptic quality) is also a major concern in food irradiation.

Another functional difference is in the way the material is packaged before it gets to the irradiator. Pallet-size loads are more difficult to treat than individual boxes and agricultural commodities are usually palletized. Foods are usually more dense than medical products leading to additional problems of achieving the penetration required without overtreating and damaging those items closest to the outside of the box or pallet. The tonnages or throughput desired for agricultural commodities will be many orders of magnitude greater than most non-food products leading to yet another significant difference between the technologies needed to satisfy the needs of each product type.

These differences are the subject of study and design interest by that part of the commercial sector that sees great opportunity in food irradiation technology. It must be stated however that there is still significant work to be done in evaluation of technical effects such as efficacy in disinfestation, shelf-life extension, delay of ripening, onset of senescence, etc. This is the case because so many commodities have not yet been studied. They must receive some minimal research at least because it is known that technical effects can vary even between varieties of the same commodity. On the other hand, I can assure you that the U.S. Department of Energy Byproducts Utilization Program work and progress in food irradiation has drawn the highest praise (and envy) in Europe, Central and South America, Bangladesh, Thailand, India, the Philippines, Indonesia and other countries I have worked with who have also been working on food irradiation because they need it even more than we do. Some countries in Europe, such as the Netherlands, France and Russia have been using food irradiation successfully on many commodities and for quite some time, e.g. froglegs, shrimp, vegetables, fruits, cereals, etc. (Attachment 1). Only potato sprout inhibition and wheat and wheat flour disinfestation have been approved in the United States for any length of time. Neither is used since chemicals are permitted and are cheaper and easier to use. Spices have "would be" facility operators are up against an allocation system from the cobalt-60 production industry. The situation is perceived by many at this time as a limiting factor in potential growth in the medical products field. Most of them feel that while irradiation will be used to sterilize up to 90 percent of medical products by the year 2000, a more plentiful supply of gamma producing isotope would certainly shorten that period.

Other areas of activity, mostly using machine-generated electron beam irradiation, have also grown significantly. Irradiation is used to polymerize numerous kinds of insulation in wiring and cabling, initial setting of green rubber before being placed into tire molds, deposition and bonding of paper coatings, production of clear plastic wrap for meat and other products, sterilization of empty flexible cartons for asceptic packaging of foods and drinks and many other such uses directly or indirectly impacting hundreds of billions of dollars worth of products. These activities are ongoing in the United States and worldwide and in a very real way the participants feel themselves part of an international community rather than a parochial one. This technology, perhaps more than any other, has had to cooperate. First, to survive any perceived association with the nuclear group by the average citizen, and then to grow into an internationally accepted technology where their products could freely move in domestic and international commerce.

There are some functional differences however between the irradiation technology for non-food items described above and food irradiation. These differences preclude simple technology transfer to food. The major differences include such items as the significantly different technical effects desired in the irradiated product. In the medical product industry, for example, a minimum dose for the sterility level desired is mandatory while the maximum dose is really only limited by the onset of deleterious effects in terms of physical properties such as strength, flexibility, brittleness, color, undesirable chemical changes, etc. In some cases the min/max ratio tolerance may be very tight but usually achievement of minimum dose is the only subject of regulation or process control.

Food however receives much closer scrutiny and a higher degree of concern because it is ingested on a recurring and long-term basis. The chemical changes, called radiolytic products, have long been of concern to the national and international regulatory and scientific communities. The literature adequately documents the research done around the world since inception of the Atoms for Peace program. Suffice it to say that more is known about the generation of compounds in and effects on the foodstuff by irradiation than for any other food process used by man now or in the recently been approved at the one megarad level in the United States and will soon be finding their way into the marketplace.

International trade in irradiated food products will be facilitated to the degree that the nations accept the Codex Alimentarius Commission's recently approved food irradiation regulations and code of practice. Many countries including Canada are in the process of accepting this one megarad dose regulation and Bangladesh accepted the complete Codex package some months ago without reservation. The United States' current approach of creeping up to the Codex standard 100 kilorads at a time may put us at an economic disadvantage in terms of balance of trade for quite some period of time.

Our lack of a food irradiation regulation is in fact a major institutional impediment to the program. Once we have a regulation, even at 100 kilorad, we can begin to credibly address the other obstacles. Consumer education has to be a major task that must be properly developed and administered. That this is so is validated by reading the comments to the U.S. Food and Drug Administration regarding the proposed regulation. Most people who have a major concern about food irradiation have it for the wrong reason or reasons. Many believe the food is radiactive, that an irradiator is like a reactor with a Three Mile Island syndrome, that the radioactive isotope itself is added to the food, that major but unknown mutagens and carcinogens are induced by the irradiation, etc. Of course, none of these are true, but we have done a poor job of public education and dissemination of technically correct information. It is easy to understand why, however. Without a food irradiation regulation--and until recently, with frustratingly little hope of getting one in one's professionally productive lifetime--there has been no incentive. Things are different now and we must get on with this critical task quickly and effectively.

Until a processor has adopted the technology, however, there is no consumer problem because there is no irradiated commodity. A processor must see a clear advantage before he will discard his current processes and put himself at financial risk. An advantage such as lower cost, better product, greater market share, diversification potential and so on will be the driver to his decisionmaking. Once he is committed to the change he will certainly help in consumer education in order to sell his product. He knows how to do that better than we do and we should help him.

Another major obstacle to program development is the lack of focus in the Federal Government itself on the technology. Some bits and pieces are being done by various Departments and Agencies but lack of real commitment, resulting in lack of sponsorship, leading to lack of funding, which then keeps good people away from the program, is in itself a self-fulfilling prophecy of failure. Some vision and foresight could have made a difference, but apparently there was not enough to go around. Congressman Morrison's bill will provide the focus and integrate the activities by placing the responsibility in a Food Irradiation Commission. It is hoped that the group will be so wisely constituted that they will have litte trouble earning the cooperation of the various Federal Departments and Agencies supporting the work.

There are obstacles related directly to technology transfer but some of the necessary programs and needed facilities being implemented to overcome them have already been cited by Dr. Gilbert. That we have hit the ground running with a 3-year head start and are well on our way is due to the responsiveness of the Armed Services and Appropriations Committees. The technology transfer program supports the needs and will provide the data which will confirm or refute the perceived validity of the incentives for further development of food irradiation technology. The agricultural and food industries need alternatives to some problem pesticides and preservatives. To say this is not to give a blanket indictment to chemicals. Nothing could be more thoughtless since we would do badly without fertilizers, pesticides and preservatives. But where problems do exist, irradiation may hold significant promise. It is not a panacea but should be considered as another tool which when useful might very well be the option of choice. It can have one or more of the potential incentives, under certain conditions, of lower cost, better product, longer shelf life, less waste, increased food supply, better nutrition, lower energy requirements and so on. It is the first major new food process in almost 100 years and is considered by many to hold great promise.

Full realization of that promise will require significant irradiation capacity since food tonnages will be so great. It is easy to reach the conclusion, when considering world-wide needs, that insufficient isotope supply will become the choke point in technology utilization. Machine-generated irradiation, when used in large facilities to irradiate products of lower density at high photon energy levels, holds great promise for successfully addressing the alleviation of the isotope shortage problems. I addressed that issue in Japan last December when I was invited to be the commentator at a linear accelerator conference sponsored by the Japan Atomic Industrial Forum (Attachment 2). My conviction is that the time will soon be here when we must use available resources more wisely. Gamma producing isotopes will be used in those facilities where the superior penetration of gammas are needed, such as in dense foods and large pallet loads. Where low density goods such as many medical products (gowns, masks, catheters, plastic ware, gloves) are treated, machine-generated irradiation would be adequate and if volumes are large, less costly. Machines can also be used to produce X-rays and gammas by impacting the electron beam into a target material (bremsstrahlung). Although the efficiencies are low in this mode, it can be useful when occasional X-rays or gammas are needed because a more dense product batch is being processed.

The machine-generated irradiation industry, both in the United States and abroad, are very much interested in their future role in the food irradiation arena. They attend the meetings, ask good questions, and many feel their time has come. I also believe that they will have an important role in the total irradiation technology activities. They will be involved directly in food irradiation with high (8 to 10 MeV) electron beams and indirectly by assuming a larger role in medical products irradiation where they will free up isotopes needed for the growth of the food irradiation industry.

In closing, I must say that it is heartening to note the renewed interest of the Committee on Science and Technology in this program. I have been involved in isotope utilization-related activities since 1972 and it was this Committee which originally nurtured the program through its infancy and helped get it off the ground. Other interests intervened however and as the needed support waned, the Armed Services Committee took on the role of moving programmatic objectives forward to the present status described by Dr. Gilbert. Their objectives of utilization of defense-related byproducts have essentially been accomplished and this program is ready for its "rites of passage"; in the U.S. Department of Energy for technology development and commercialization oversight, to the U.S. Department of Agriculture for needed research support and implementation, to agencies such as the U.S. Agency for International Development where the technology is a powerful tool for the problems of worldwide food hunger and to the U.S. Department of Commerce where the export potential of United States technology, equipment and commodities needs someone's undivided attention.

ABC2/017

Attachment 1

List of Clearances for Irradiated Food

(either on an unconditional or restricted basis)

YEAR OF FIRST CLEARANCE IN A COUNTRY FOR A GIVEN FOOD ITEM OR GROUP OF RELATED PRODUCTS

PRODUCT \ COUNTRY	ARGENTINA	AUSTRALIA	BELGIUM	BULGARIA	CANADA	CHILE	CZECHOSLOVAKIA	DENMARK	FRANCE	GERMANY, FED. REP.	HUNGARY	ISRAEL	ITALY	JAPAN	NETHERLANDS	PHILIPPINES	SOUTH AFRICA	SPAIN	THAILAND	UNITED KINGDOM	URUGUAY	U.S.A.	U.S.S.R.
COALFISH, WHITING AND PLAICE FILLETS															76								
RYE BREAD															80								
RICE AND GROUND RICE PRODUCTS															79								
PAPAYA																	78						
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DRIED FRUITS				72																			66
GARLIC			80	72					77				73				78						
ONIONS			80	72	65		76		77		73	68	73		71 75		78	75	73				67 73
POTATOES	78		80	72	60	74	76	70	72	74	69	67	73	72	70	72	77	69			70	64	58

Attachment 2

Commentary on Proceedings on the Linear Accelerator Conference held at Lake Kawaguchi, Fuji
December 9-10, 1983

by
Jacek S. Sivinski, Director
Irradiation Technology Programs
CH2M HILL, U.S.A.

Mr. Chairman and Gentlemen:

I am honored to have been invited to participate in this distinguished gathering as a commentator. My special thanks go to Professor Tabata for arranging my invitation.

So that you may better appreciate what I am going to say let me briefly describe my current responsibilities. My firm and I are very active as a services support contractor to the Albuquerque Operations of the United States Department of Energy (U.S. DOE) in the DOE Byproducts Utilization Program (BUP). This is a program that pursues vigorously the objective of utilizing reactor byproducts for the benefit of mankind and thereby making them an international resource, rather than considering them an international liability. The specific applicability to the type of activities being described in this conference is the isotope cesium-137 which is a gamma producer and, under certain circumstances, can be used interchangeably for producing some of the effects described by the equipments being discussed in this conference. Our particular emphases currently are in 1) sludge irradiation which permits municipal sludges to be used in a beneficial way as a soil conditioner and fertilizer rather than treated as a liability to be disposed of at additional cost to the taxpayer, and 2) in the much larger area of food irradiation. These expanding areas of activity are going to require significantly increasing amounts of ionizing energy and I am firmly convinced that the rate of increase will be much higher than the world capability to produce the required isotopes to meet these projected needs. You gentlemen understand your long term developmental needs in other areas much better than I do, but in addition to those uses which Dr. Tanaka has just mentioned, I want to tell you why the need for accelerators is going to become quite critical in the short term.

As you know, ionizing energy is already used extensively in medical products sterilization worldwide. In the United States approximately 20 to 25 percent of medical products are now sterilized using ionizing energy and the balance are done with chemical fumigants; the major one being ethylene oxide (ETO). ETO has been on the U.S. Environmental Protection Agency rebuttal presumption against registration

(RPAR) list for some period of time, but very recently the U.S. Occupational Safety and Health Administration (OSHA) have changed their regulations to decrease the integrated daily worker exposure level from 50 parts per million (ppm) to 1 ppm. This 50 fold reduction is going to be costly to implement and in certain instances may become prohibitive for further use of ethylene oxide. Because many parts of the medical industry have forseen this there has been a significant shift toward medical products sterilization using ionizing energy. That shift will now accelerate very rapidly and it is already the case that the Atomic Energy of Canada, Limited (AECL), has put its customers on an allocation basis for isotope procurement. There is a significant part of the medical products treated which are low density in nature and could very effectively utilize accelerator technology in lieu of gamma technology.

A potentially larger area for use lies in the need for new alternatives in the agricultural commodity industry. As an example, ethylene dibromide (EDB) currently is used for disinfestation of fruits and vegetables for meeting quarantine requirements for Mediterranean fruit fly, Mexican fruit fly, Caribbean fruit fly, Queensland fruit fly, melon fly, mango weavil, etc. and has also been used as a soil nematicide. It has historically been used for fumigation of grains, spot fumigation of milling equipment, treatment of felled logs for beetles, etc. However, when ETO began to be found in well water in Hawaii, California, North Carolina, Florida, etc. a real concern developed on its further use. Because it was such an effective fumigant for quarantine purposes it is used extensively throughout the world and testing is showing high residuals in many fumigated fruits and vegetables. ETO however, is now considered a very dangerous chemical and the EPA imposed an immediate ban on further use of this chemical on September 30, 1983, except for fruits and vegetables, where its use will be banned completely after September 1984. The implications for severe restrictions in international trade in agricultural commodities are significant. The future of chemical fumigants in general is not bright and hopes for short term viable options using other chemicals for EBD replacement are not high.

Another chemical that is also used extensively on those agricultural commodities which tolerate it, such as dried fruits, tree nuts, vegetables, apples, etc. is methyl bromide. It is effective against naval orange worm, codling moth, Indian meal moth, and other such moths. Some of these commodities that are stored for extended periods are repeatedly gassed, with a resulting bromide residue build-up. The bromide residue impedes international commerce. Irradiation after packaging for export instead of a final gassing could very effectively keep these bromide residues down and provide new export markets. It is also anticipated however, that the use of methyl bromide may become severely curtailed as the attention of the investigative community begins to center on this chemical after the ethylene dibromide crisis has been resolved. I know that Canada is already seriously reviewing its use and research is being done in The Netherlands on the potential carcinogenicity of methyl bromide.

The U.S. Congress is funding technology transfer activities and facilities in order to move the developed irradiation technology into the public sector where it can be utilized over a broad spectrum. One of the facilities funded will be a large fruit and vegetable irradiation demonstration project in the Miami, Florida, area for the U.S. Department of Agriculture. Tropical fruits, celery, papaya, citrus, mango, lettuce, etc. will be studied at near-commercial scale in order to ensure efficacy for the insect control required and also demonstrate the lack of phytotoxicity on the agricultural commodity itself. A pork irradiation demonstration facility leading to trichina-safe pork in the U.S. by 1987 is also funded and will be constructed in conjunction with a university having a very good meat laboratory and a good food science department for the further development of various products which do not have to be treated chemically or be heated or frozen in order to meet consumer safety requirements. A transportable cesium irradiator for validating the efficacy and phytotoxicity effects onsite in a area of production and processing is also under construction. This facility will be moveable all over the U.S. and it is anticipated that it will see a large amount of use in areas as widely diversified as meats, fruits, vegetables, fish, shellfish, etc.

Another point to remember is that gamma irradiation is probably the option of choice in those food irradiation programs where product densities are high and throughputs are large. Where accelerators can be used in current programs using isotopes, the switch should be made and the isotope freed for these special uses. This is not to say accelerators do not have a role in food irradiation, they do and their role will grow rapidly. I do say that accelerator and isotope roles in the future should be more finely focused thereby using the right tool for the right job to the benefit and growth of both systems. We simply won't be able to afford the luxury of using them as interchangeably as we do now.

The worldwide interest in ionizing energy activities and particularly in food irradiation, is well exemplified in the part of the world where this meeting is being held. Japan has funded major food irradiation programs for a number of countries under a Regional Program for Food Irradiation (RPFI) under a Regional Cooperative Agreement (RCA) in conjunction with the International Atomic Energy Agency. Significant progress has been made and many countries such as Indonesia, the Philippines, Thailand, Bangladesh, Pakistan, etc. have developed their food irradiation programs with the help of Japan to the point that they are now ready to begin transferring their technology into the private sector. Such cooperative programs provide a very good example for the rest of the world on how to achieve major accomplishments with minimum funding through cooperative modes.

Another irradiation area that is receiving increased interest is a methodology for dealing with biological toxic wastes from hospitals and laboratories. Incinerators are energy intensive polluters and better ways of reducing the human health hazard with less impact on the environment are being investigated.

My final comment would be that whether the U.S. or Japan accepts food irradiation technology in the very near future is no longer a necessary condition for world acceptance of the technology. The rest of the world will go ahead because they must do so in order to compete effectively and to survive in world markets. Another major reason however, is that the benefit to the citizens of each of these countries will be significant in terms of increased public health and welfare, lower costs, better nutrition, and an improved quality of life. It is my opinion gentlemen, that both you and linear accelerators have a very bright future in the short term and a golden opportunity to contribute significantly to the welfare and peace of the world.

I appreciate the opportunity to be with you for these two days and for the fact that you have contributed significantly to my education. I hope perhaps that I might also have brought some new information to you. Thank you.

Mrs. **LLOYD**. Thank you very much, Dr. Sivinski. We do appreciate your testimony as well as your attachments that you've also provided.

Dr. Tingey, would you proceed?

STATEMENT OF DR. GARTH L. TINGEY, SENIOR RESEARCH SCIENTIST, BATTELLE PACIFIC NORTHWEST LABORATORY

Dr. **TINGEY**. Thank you very much, Madam Chairman. It's an honor for me to be here today and I've really enjoyed the enthusiastic support from you and other Congressmen who have spoken today.

Mrs. **LLOYD**. I think it is really a source of enthusiasm to think that we can move ahead with such positive programs that will not only enhance our lives, but that we will see in the next generation as well, that we have also made a contribution.

Please proceed.

Dr. **TINGEY**. Almost all of the food that Americans consume is processed in some ways that produce chemical changes in the food. These processes include freezing, canning, drying, smoking, salt-curing, and cooking. Irradiation of foods for the purpose of disinfestation, shelf life extension, or preservation is similar in that limited chemical changes may occur. However, irradiation in general deposits much less energy in the food than many of the other processes that we are aware of and that I have mentioned, and thus the changes in the chemistry are also minimized.

Gamma rays and x rays are forms of electromagnetic radiation. That's been referred to earlier. That includes radio waves, microwaves, and even visible and ultraviolet and infrared light. Gamma rays and x rays have sufficient energy to cause ionization, and thus the chemical changes are caused by ionic and free-radical reactions, whereas lower energy forms of electromagnetic radiation produce chemical changes by vibration or electronic excitation.

I think we must teach the public that it's not appropriate to compare irradiated foods with tooth x rays or chest x rays because no nuclear activation occurs with gamma radiation, and the product does not become in any way or to any extent radioactive.[1]

Mrs. **LLOYD**. Dr. Tingey, just to reinforce that statement, would you just repeat the last sentence again, please?

Dr. **TINGEY**. OK. We must teach the public that it is not appropriate to compare irradiated food with tooth x rays or with chest x-rays because no nuclear activation occurs with gamma radiation, and the product does not become in any way or to any extent radioactive.

Mrs. **LLOYD**. Thank you.

Dr. **TINGEY**. Pacific Northwest Laboratory is currently conducting a DOE-sponsored experimental program in conjunction with the Department of Agriculture, specifically the Department of Agriculture laboratories in Washington State, and also with some of the food processors and agricultural organizations in the State. And perhaps I should note here that the Pacific Northwest Laboratory is a contract research organization for the Department of Energy at the Hanford site.

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[1] See letter from Dr. Tingey, p. 193.

The goal of this program is to evaluate the potential benefits of irradiation of agricultural products in the Northwest. Initial efforts have concentrated on irradiation of apples and cherries to disinfect them of codling moths and cherry fruit flies. Irradiation appears to be equally and, I think, generally more effective than presently-used fumigation techniques, and it is less harmful to the fruit and does not leave a chemical residue.

I have a couple of vu-graphs here that I would like to show briefly to indicate the effectiveness in removing the infestation by cherry fruit flies and by codling moths.

This first vu-graph shows the irradiation of cherries that have been specifically infected with cherry fruit flies, as a function of dose. You should note that the maximum dose that we have irradiated is less than one-fifth of the dose proposed by the USDA for approval of irradiation of food. The first is the control with no irradiation whatsoever, and these cherries—for 100 pieces of cherry, we had 109 pupae develop for each 100 fruit; and with irradiation, you can note that in the pupae stage there was a significant, very marked decrease in the number that pupaeted, by dose, up to 17.4 kilorads.

Perhaps of more importance from a quarantine point of view is the emergence of adults. You will notice that with the exception of one fly that seems to be some cross-contamination, we have no emergence of adults at all, even at the lowest dosage, which was 3.5 kilorads, in the cherry fruit fly.

The next one, briefly, describes the codling moth kill. To reach quarantine requirements, again, in the codling moth—and I should mention here that codling moths are difficult to kill in cherries under low temperature atmospheric control because they are in what's called the diapausing stage, which means that they are essentially dormant, their respiratory rate is very low, almost nonexistent—and you'll note here, again, it was about one-fifth of the dose proposed by FDA, and we were able to meet quarantine requirements with codling moths in both the nondiapausing, or active stage and the diapausing, or dormant stage.

The supply of sources of radiation has been discussed and stressed to some extent, and it is very important, I think, that we look again at this. Now, Dr. Gilbert showed a graph that was, I think, important and I would like to just emphasize that by showing much of that data again, with an indication of how many irradiators we could get from these sources. I should say—and it is written into my testimony—that cesium-137 is one of the sources available at Hanford through material that has already been collected from the byproduct of defense nuclear fuels. We have 77 megacuries—77 million curies—of material already encapsulated; and when accepted by the Nuclear Regulatory Commission, would be available for use in irradiators—accepted and available for lease or sale by the Department of Energy. That 77 megacuries could enable us to make about eight irradiators; that's assuming, of course, about 10 megacuries per irradiator.

In addition, we expect about 40 million more curies to come from future Purex work, and that would bring the total number of irradiators up to 12. The Savannah River waste, which is not readily available to us but which should be studied and considered for encapsulation for irradiators, in my opinion—not necessarily, I guess, the opinion of the Department of Energy, but certainly mine—should be considered for encapsulation for irradiators, which would allow us about another 10 irradiators; and then Dr. Gilbert showed very effectively the large quantity of material in commercial waste—again, not available to us unless we have some spent fuel treatment processes that would allow us to collect the cesium-137 or if we have reprocessing of commercial fuel. And you can see the very large number of commercial irradiators that could be supplied.

The question was asked earlier what the opinion of the market was. My own personal opinion is that even just for medical irradiators, we will see requirements for all of the material that is available now, including the future Purex material, and we will need much of this material from other sources to be able to meet present demand. And when food is accepted for irradiation, then that demand will grow very markedly and exceed what we have here.

I'd like now to briefly discuss the effect of recovery of nuclear byproducts on nuclear waste management. The disposal of nuclear waste, as I think all of us are aware, is currently very much in the public mind.

As I mentioned in my testimony, cesium-137 is one of the major fission products found in the nuclear fission of uranium. As such, its removal from the fuel or waste reduces markedly the amount of radioactivity and heat generated in the fuel, or so-called waste from reprocessing of that fuel.

I have a bar graph that I would like to show at this time that reflects graphically the point that I am trying to make. You will note that the graph on the left shows the major heat-producing materials in nuclear waste. The bottom, in red, is cesium and barium, which is a daughter product, a short-lived daughter product of cesium; and when you remove cesium, you also remove the barium. It has approximately half of the total heat being generated by cesium and barium.

In the orange, strontium, and yttrium, which is also recovered from the waste at Hanford and is a valuable byproduct in itself—not for irradiators, but for heat producers and power generation, remote power generation; it supplies nearly all of the rest. So if cesium and barium are removed, in addition to the strontium and yttrium—if they are removed from the nuclear waste, then you have about 5 or 6 percent of the original heat left in the waste that could be disposed of.

On the right I have plotted a similar plot, showing the radioactivity in kilocuries per tonne from that—by the way, I should emphasize that these numbers are for power reactor fuels 10 years after discharge, but defense fuels, though much lower in both heat and radioactivity, the ratios are about the same—but again, if we remove the cesium and barium and the strontium and yttrium from the waste, then we will leave on the order of 4 or 5 percent of the radioactivity in the waste that will need to be disposed of.

In summary, I would like to give a few recommendations; again, not necessarily the recommendations of the Department of Energy, but certainly things that I consider important for this committee to consider.

First, I think there needs to be a continued support of research and encouragement for recovery and encapsulation of cesium-137 from defense fuels.

Second, we need to support studies to ensure the safety and licensibility of present and future byproduct capsules.

Third, define and produce optimized capsules for byproduct use. The capsules that are currently produced were produced, as Dr. Gilbert indicated, over a decade ago—or started to be produced—and the main purpose then was to remove these highly radioactive and heat-producing isotopes from the nuclear waste stream. Future capsules ought to be optimized for use in a by-product application; in the case of cesium, for irradiators.

The fourth recommendation is to encourage recovery of by-products from power reactor fuels, especially if we return to reprocessing or if spent fuel treatment is required.

The fifth recommendation is that we continue support of demonstration irradiators until the technology is sufficiently certain to encourage and stimulate private industry.

Lastly, to evaluate the potential and desirability of producing cobalt-60 in the United States to provide a reliable domestic supply and to meet the needs of an expanding demand for source material today.

It has been a privilege to present this summary and I hope that it has some meaning to those who are interested in this topic.

[The prepared statement of Dr. Tingey follows:]

TECHNOLOGY OF FOOD IRRADIATION*

G. L. Tingey
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I am pleased to have the opportunity to testify on the development and commercialization of food irradiation. This technology holds the promise of contributing markedly to our ability to expand the world's available food supply, to assist in expanding our near-term export market, and to protect the environment by disinfesting a variety of food products.

BACKGROUND

Almost all of the food that Americans consume is processed in ways that produce chemical changes in the food. These processes include freezing, canning, drying, smoking, salt-curing, and cooking. In the future, irradiation may also be used. It is one of the least energetic treatment processes; thus, chemical changes to the product are often less extensive. The need for irradiation as a food treatment process for disinfestation is growing because of the hazards associated with some chemical fumigants; and extension of shelf life is clearly needed, especially in Third World countries. Therefore, the potential for growth of irradiation processing of food appears to be promising both in the United States and worldwide. In order to accommodate this growth, the need for supply of radiation sources demands our attention.

Gamma rays and x-rays are forms of electromagnetic radiation, which also includes radiowaves, microwaves, and even visible light. Gamma rays and x-rays have sufficient energy to cause ionization and thus cause chemical changes by ionic reactions, whereas lower energy forms of electromagnetic radiation produce chemical changes by heating and electronic excitation. In contrast to irradiation with neutrons, no nuclear activation occurs with gamma irradiation and the product does not become in any way or to any extent radioactive.

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* Testimony before the Subcommittee on Energy Research and Production, Committee on Science and Technology, U.S. House of Representatives, July 26, 1984.

IRRADIATION OF NORTHWEST AGRICULTURAL PRODUCTS

Pacific Northwest Laboratory (PNL) is currently conducting a DOE-sponsored experimental program in conjunction with the U.S. Department of Agriculture (USDA) laboratories in Washington State. The goal of program is to evaluate the potential benefits of irradiation to the agricultural industry in the Northwest. The near-term objective is to construct a demonstration irradiator that could be used to irradiate a variety of products in sufficient quantities to establish the market potential and to stimulate public acceptance. Initial efforts have concentrated on irradiating apples and cherries to disinfest them of codling moths and cherry fruit flies. Irradiation appears to be the treatment of choice to meet the quarantine requirements for export to the Far East. Tests to date indicate that a gamma dose of 20 to 30 krads is sufficient to meet quarantine requirements with no detrimental effect to the fruit. In fact, shelf life may be extended slightly. Tables I and II show the effects of relatively low doses of irradiation on cherry fruit flies and codling moths. Studies are continuing on these and other products as a joint effort by PNL, the USDA laboratories in Yakima and Wenatchee, Washington, and other interested agricultural organizations.

RADIATION SOURCES

Sources for food irradiation include gamma-emitting isotopes and radiation-generating machines. The primary isotopes of interest are cobalt-60 and cesium-137, a byproduct from defense and commercial nuclear fuels. Cobalt-60 has a half-life of 5.27 years, and cesium-137 is less energetic than cobalt-60 but has a half-life of 30.2 years.

Radiation-generating machines that produce high energy electrons have been developed and are currently used to a limited extent for irradiation of medical products and spices. These machines may be preferred over isotopes if the material to be irradiated is of low density and if the near-surface dose is sufficient. However, high energy electrons have a limited penetration depth and are ineffective on high density or thick samples. Although high energy can be used to generate more penetrating gamma rays or x-rays, this conversion is quite inefficient.

Cobalt-60 is generated by the capture of a neutron by cobalt-59 in a nuclear reactor. Almost all of the world supply of cobalt-60 is presently supplied by Atomic Energy of Canada Limited. Only about 1 million curies/year are generated in the United States, and this amount comes from a government-owned materials test reactor. Utilities have shown little or no interest in producing cobalt-60 in power reactors. The acceptability of producing additional cobalt-60 should be investigated to give a reliable domestic supply and to meet demands of an expanding market for gamma sources.

Cesium-137 is one of the major fission products generated in nuclear fission reactors and, thus, is a byproduct from both power and defense reactor fuels. To aid waste management, this isotope has been recovered and encapsulated from the defense reactor waste at Hanford since 1967; 1575 capsules, containing about 86 million curies of cesium, have been produced. Material from a few of the capsules has been used for various purposes and radioactive decay has occurred, leaving a current inventory of about 77 million curies. These capsules contain radioactive cesium as cesium chloride doubly encapsulated in 1/8-in.-thick stainless steel cylinders. They have been tested for mechanical strength, corrosion resistance, vibration, and in the ability to withstand high temperatures in accidental fires. In addition, tests are under way to examine the effects of thermal cycling and high-temperature swelling and to define the temperature limits for long-term operation. The results of the tests indicate that the capsules will withstand the irradiator operating and projected accident conditions with a wide margin of safety. In addition, the capsules will be monitored and selected ones will be periodically examined to assure their integrity.

The present U.S. demand for isotopes for irradiation of medical products and spices exceeds availability. This demand is expected to grow. Furthermore, as irradiation of food becomes a reality, the demand is expected to increase markedly. To meet the needs for radiation sources, we must take advantage of all three types of sources--cobalt-60, cesium-137, and radiation-generating machines.

At present, DOE has more requests for cesium-137 sources than are available. As previously mentioned, there are approximately 1500 sources containing about 77 million curies stored at Hanford. An additional 40 million curies will be separated from Hanford defense waste through 1991. Although current plans stipulate disposal of this material, it could be made available if there is demand for it. The stored defense nuclear waste at Savannah River contains about 100 million curies with another 100 million to be generated through the year 2000. However, facilities for purification and encapsulation are not currently available at Savannah River. A program to evaluate the most cost-effective way to make this cesium-137 available for irradiation sources should be undertaken.

The largest source of byproduct cesium is in the spent fuel from commercial power plants where an estimated 500 million curies are contained. This amount will increase to about 11 billion by the year 2021. Recovery of the cesium-137 from spent fuel can be considered only if fuel reprocessing were undertaken or if spent fuel disposal requires removal of the most volatile radioactive species before storage. The potential availability of the byproduct cesium is summarized in Table III along with the estimated number of irradiators that could be supplied by this source. Presently available cesium would supply only eight average-sized (10 MCi of cesium-137) irradiators. Thus, at best, the present cesium could only aid in meeting the immediate demand; and additional cobalt-60, cesium-137, and radiation generating machines would be necessary for future requirements.

DOE and its contractors are presently engaged in gathering the data necessary for U.S. Nuclear Regulatory Commission (NRC) approval to use the present cesium-137 capsules in irradiators. The NRC approval along with acceptance of food irradiation by the Food and Drug Administration will assure an increasing demand for all irradiation sources.

WASTE MANAGEMENT BENEFIT

During the first 200 years of storage of nuclear fuels or nuclear waste, the major radiation and heat-producing isotopes are cesium-137 and strontium-90. When these two elements are removed from 10-year-old fuel, the heat produced and the radiation emitted will be reduced to about 6% of their value with these two elements included (Table IV). Thus, removal of cesium and strontium could produce major waste management and disposal cost savings and would result in a waste with much less radioactivity and heat during the early years of disposal. In summary, further development of irradiation technology for food and other commodities, using all sources of irradiation, will clearly be a great benefit to society and, at the same time, lessen the challenges in handling and disposal of nuclear waste.

RECOMMENDATIONS

As has been shown in this and previous testimonies, much of the research and development has been completed to assess the viability of food irradiation. There remains, however, the important areas of supplying domestic sources of gamma-producing isotopes and the need to demonstrate to the public the benefits and safety of this technology.

Since the most ready supply of cesium-137 comes from government and defense fuels, its supply is solely dependent upon government policies and decisions. The present cesium-137 capsules need to be licensed. Obtaining the necessary data to ensure their safety and licensability is a natural role of the government. Since the demand for this isotope has become better defined, cesium-137 recovered in the future should be enclosed in capsules optimized for irradiator use. Design of optimum capsules and development of fabrication techniques and equipment should be part of the federal program. Furthermore, the entire inventory of spent nuclear power fuel is controlled by the federal government as outlined in the Nuclear Waste Policy Act. Thus, as policies are established for management of the spent fuel or waste, consideration should be given to the recovery and use of the nuclear byproducts.

The present DOE policy stimulates the development of food irradiation by participating in the construction of demonstration irradiators. The purpose of these demonstrations is to evaluate irradiator designs, to supply sufficient material to stimulate public acceptance in the product, and to test acceptability to foreign markets. This policy should be continued for a period of time sufficient to complete a thorough evaluation of this technology.

TABLE I. Control of Cherry Fruit Fly

Dose (krad)	Mean Number/100 Fruit	
	Pupae	Adults
0	109	78.0
3.5	44.5	0
5.3	38.5	0
7.0	25.0	0
10.5	19.0	0.5
17.4	9.0	0

TABLE II. Control of Codling Moth (dose required for quarantine security)

	Nondiapausing Larvae	Diapausing Larvae
Prevent Adult Emergence	21 krad	23 krad
Prevent Normal Emergence	14 krad	15 krad

TABLE III. Estimated Inventory of Cesium-137

Sources	Million Curies	Number of Irradiators Fueled(a)	
		No.	Cumulative
Hanford			
As of 1984	77	8	8
Additional to 1991	40	4	12
Savannah River			
As of 1984	100	10	22
Additional to 2000	100	10	32
Spent Fuel			
As of 1984	500	50	82(b)
Additional to 2021	11,000	1,100	1,182(b)

(a) 10 MCi of cesium-137 per irradiator.
(b) Assumes reprocessing or major waste treatment.

TABLE IV. Major Heat and Radiation-Producing Isotopes in Nuclear Waste(a)

Isotope	Heat Generation (watts/tonne)	Radioactivity (kCi/tonne)
Cesium + barium	430	160
Strontium + yttrium	370	115
Curium 30	1	
Americium	7	0.2
Promethium	3	10
Total (including those not shown)	860	290

(a) 33,000 MWd/tonne; 10 years after discharge.

Mrs. LLOYD. Well, thank you both very much. I think you can look forward to this committee asking you to give us more of your advice a little bit later on.

Dr. Sivinski, how do the economics of operating an irradiating facility with cobalt and cesium-137 compare?

Dr. SIVINSKI. The studies that we have done, looking at cobalt versus cesium, based at the current price of 10 cents a curie indicate that, on a present net worth basis, a 20-year life of a facility, one could pay up to like 40 cents a curie to be equivalent to the dollar-per-curie average that is now being charged for cobalt by Atomic Energy of Canada, Ltd. So it is very useful.

However, an overriding factor, since I work with many other nations through the International Atomic Energy Agency and the Food and Agricultural Organization, and the World Health Organization, ongoing programs there, they are very—the rest of the world is even more interested in our cesium than we are, and for very good reason. The half life of cesium is 30 years. The half life of cobalt is essentially 5 years. That means that for a cobalt facility, you have to shut it down and replenish about 12 percent of the isotope every year; and in a low-tech country, like the lesser developed countries, that is a major event. It is certainly not equivalent to the end of the world, but it is significant.

With cesium you only need to do that every 5.2 years or so, 5.5 years, and that's terribly important to them. So there is interest in the whole world for the use of cesium for that particular reason; not only for economics, but also the technology, the simpler technology.

Mrs. LLOYD. Even if the upfront costs would be more on the long haul, it would be more advantageous?

Dr. SIVINSKI. Right. Well, one would have to balance that out; you can't speak for a given country.

Mrs. LLOYD. Do you agree with that, Dr. Tingey?

Dr. TINGEY. I think the importance of the half life is certainly a very important consideration. Though there are differences in design that will be required, I certainly think this use of cesium is important to our continued development of this process and we should certainly proceed with this, especially in light of the shortage of isotopes at the present time.

I'm not sure I answered specifically the question that you wanted me to address.

Mrs. LLOYD. Your answer was well taken.

Then cesium from the United States could compete with cobalt, most of which is supplied by the Atomic Energy of Canada, on an international market?

Dr. TINGEY. Yes. I think it certainly should compete.

Mrs. LLOYD. How significant is this market?

Dr. TINGEY. And I think it will compete, provided we take full advantage of the savings that could accrue to waste management by removal of the cesium. I emphasized that point in my last bar chart, and I think——

Mrs. LLOYD. Yes, that point was well taken. I think reprocessing is going to solve a lot of our ills.

Dr. TINGEY. If we take full advantage of the savings by removal, then cesium will compete, in my opinion, with the cost of cobalt which is manufactured specifically for irradiators by irradiating cobalt-59 in a reactor.

Mrs. LLOYD. Dr. Tingey, I have the five recommendations that you gave, the directions that you think we should move as a nation. I'd like for both of you to expand on other thoughts or other ways that you think the Federal Government should assist in the commercialization of food irradiation, the technology.

Dr. SIVINSKI. Well, I think we ought to determine——

Mrs. LLOYD. In education? Let's talk about the other dimensions.

Dr. SIVINSKI. That's right. The consumer education is a very thorny issue, and there are two sides to the coin. I have given papers previously which said, really, it's not the most important issue in terms of consumer acceptance because, unless a processor feels the need, he's driven to going into irradiation for some reason; like you can either capture a larger share of the market by having a better product or a cheaper product, or it puts him in a more competitive position, or something—he has a tremendous investment in his distribution network, his good name, his processing technology, his people. And in order to change it, he has to have some very valid reasons. Until we can help him to realize these new reasons, the consumer is never going to see the product.

On the other hand, the processor is not going to put himself at financial risk until such time as he is convinced that the consumer will accept that product. Now, once he has decided that, then he can do that better than we can in the scientific area because those people on Madison Avenue have us buying most of the things that we can afford, and many things that we can't. They know how to do that very well, and we should help them do that.

But I think that your point that you made previously to one of the other witnesses, Madam Chairman, is very important. I think that the U.S. Department of Agriculture has to insert itself into that catch-22 situation in such a way that some meaningful progress can be done. I think that your point is well taken, and I think that there should be a concerted effort inside Government to assist with both the processor and the consumer education programs; and now that we are going to have a regulation forthcoming, hopefully very soon, this is an appropriate time and a very timely thing and we ought to get on with it, because time is of the essence.

Mrs. LLOYD. Thank you very much. Thank you both for your testimony and your time.

I want to express my thanks to all the participants here; this has been a rather lengthy hearing, but I think all of you will agree with me—obviously you do, because you are still here—that this has been a very worthwhile, a very informative hearing.

Our last panel includes Dr. Allan Chin, president of Radiation Sterilizers, Inc., and Frank Fraser, who is vice president of Radiochemical Co. of Atomic Energy of Canada. And I'm sure his ears have been aglow when we've been talking about Atomic Energy of Canada, Ltd., so now it is your turn.

Please proceed. It's usually our procedure to go from my left to right, but since we've been talking about our neighbors in Canada for so long I think that we'll go first with Mr. Fraser if you don't object, Mr. Chin.

Thank you.

Mr. CHIN. That's fine.

STATEMENT OF FRANK FRASER, VICE PRESIDENT, RADIOCHEMICAL CO., ATOMIC ENERGY OF CANADA, LTD.

Mr. FRASER. Thank you very much, Madam Chairman, for the opportunity to address this hearing to examine the status of the technical infrastructure required to support domestic food irradiation.

You know, Canada has heard—a lot of words have been said about Canada, but Canada is a northern neighbor; and I'm glad you said "neighbor," because there are 3,000 miles of border there that are not guarded. When we talk about domestic treatment of food in Canada or the United States, I feel that Canada and the United States are both trying to achieve the same thing and there are no barriers in there, and we are trying to build this thing together for the benefit of mankind. I'd just like to make that statement to start.

Mrs. LLOYD. I certainly appreciate your thoughts and your interest, and I certainly share your enthusiasm.

Mr. FRASER. Thank you.

There are two areas I would like to address. First, we do have a problem with mail; I just got my letter this morning, here, delivered here, so I have a few problems, but I've been able—I will be able to provide you with something that is of interest.

Mrs. LLOYD. If I may interrupt just one more time, then you may proceed; but we will give you every opportunity to submit additional statements for the record, and we may also have some questions for you that we would like for you to answer for the record, if you would consent.

Mr. FRASER. Please do.

Mrs. LLOYD. Thank you. Go ahead.

Mr. FRASER. I would like to address, first of all, the cobalt situation, the one of supply. I have heard a lot of talk about the concerns that people have. We do have a situation now in Canada where demand and supply are out of phase, but I'd like to address this right now. Part of this is a paper that I gave at our seminar; but in reviewing the overall cobalt-60 supply situation for industrial irradiator use, AFCL has shipped over 100 million curies of cobalt since the commissioning of our first cobalt-60 therapy unit in October 1951. The use of this cobalt can be categorized into three major areas: The first for cancer therapy; the second for self-contained research irradiators; and the third and largest application, for the sterilization of medical disposable products.

Of the total cobalt-60 shipped to date, approximately 13 million curies have been shipped for cancer therapy equipment; over 100 million curies for industrial irradiators; and the balance for research. One can conclude from the above that gamma radiation processing is well established and is experiencing excellent growth. As a matter of fact, close to 50 percent of the total curies shipped for industrial purposes has been dispatched since May 1980.

We have reviewed the past cobalt-60 supply situation, and I have taken the liberty to highlight—I will be highlighting a few statistics to emphasize the magnitude of this business. What about the future supply of cobalt-60? I think everybody wants to hear about that. All the cobalt referred to in this talk was produced at AECL's NRU and NRX research reactors at our Ontario HydroPickering A nuclear power generating station where there are four reactor units in operation. Currently, 80 to 90 percent of our cobalt supply is produced by Ontario Hydro.

Now, in those particular plants, two plants were shut down for retubing and will be operating again in a short period of time, within a year or slightly over a year; however, that has been a slight setback to us. But I'll tell you how we have taken steps to remedy the situation.

The potential future supply of our energy source will primarily be from three new electrical power generating stations scheduled to be in operation by 1990. Two of these stations, Bruce B and Pickering B, will be in operation within the next year; in other words, they are both in operation now. Bruce B is on stream now producing cobalt, and so is Pickering A. And the Darlington station will be coming on later in the 1980's, close to the 1990's.

The Bruce B station will operate four reactors, each with a nominal cobalt-60 production capacity of 5 million curies. That means they can produce 20 million curies in that station. Pickering B will bring on stream three reactors with a nominal combined cobalt-60 production capacity of 10 million curies. The Darlington station will operate four units similar to Bruce B, and will have a total nominal capacity of 20 million curies.

In total, the 11 new reactors described, along with 4 existing Pickering A units, have a potential annual cobalt production capacity of 63 million curies.

We have also looked at purchasing other supplies of cobalt. We are now in the process of negotiating with Quebec Hydro for up to 3 million curies annually, and also with the Argentina plant which we have supplied for producing cobalt.

Ontario Hydro produces the major portion of the world's cobalt-60 supply. You irradiate the cobalt in the reactor adjuster-rod positions; that means it is a byproduct of Canadian CANDU reactors. If there wasn't cobalt in there, they'd probably have Stainless Steel doing the job.

The number and orientation of cobalt targets contained in each adjusternrod is specifically designed to minimize fuel burnup and to produce cobalt-60 efficiently.

Now, there is another side to the supply of cobalt-60 from Ontario Hydro, and that is that there is a possibility to produce in the order of 30 percent more cobalt in each reactor. However, the incremental cost of this cobalt would be higher than the cobalt produced under the current and planned optimum conditions.

In addition to that there is the possibility, in producing cobalt in the fuel channels of certain reactors—one particular group can produce up to 32 million more curies of cobalt. So we can say that we can have—by 1990, we can be producing 100 million curies of cobalt.

The demand for cobalt-60 in the past has been substantially for medical disposable products manufacture. Today there are 70 million curies installed in facilities processing goods. We estimate this number to increase to 200 million curies in the next 10 years, at which time we believe that more than 70 percent of all—between 60 and 70 percent of all gamma-sterilized medical disposable products will be radiation sterilized. When I say gamma, it doesn't matter if it is from cesium or from cobalt, but I feel that there is going to be a large growth in that area.

If our forecasts are correct, it means that we in AECL will have to ship over 300 million curies.

Throughout this period we expect two new gamma processing applications to emerge; namely, food preservation and waste treatment. To satisfy the 10-year cobalt demand we require, and I'm going to read this again, to satisfy the 10-year cobalt-60 demand we will require approximately 43 million curies for food processing and 45 million curies for waste treatment. Therefore we see the total demand for cobalt-60 over the next 10 years to be in the order of 400 million curies. The supply of cobalt-60 for this same period, based on the nominal supply from Ontario Hydro, AECL and from other sources, approximates 500 million curies. If we add to this the potential of increasing Ontario Hydro's production by 30 percent, the available cobalt-60 for this period is estimated to be in the order of 600 million curies. I have not included in here the possibility of producing 32 million curies a year in fuel channels; that's not included in this.

Both of these figures meet the market demand. However, I must point out that while we are confident in the overall number presented, we have not as yet found a formula to predict a rate at which the industry will grow. We may find, for short periods, supply lagging rather than leading demand, resulting in longer than normal deliveries.

That's what I'd like to say about cobalt. I think it would be of interest to bring you up to date on what Canada is doing with respect to food irradiation.

Oh, before I leave this, there was a statement made that the half life of cesium was very beneficial. Can I——

Mrs. **Lloyd**. I was just going to ask you about that.

Mr. **Fraser**. OK. When you talk about the half life of cesium being beneficial, when people are putting up a facility, like Mr. Chin, for example, he will require so many curies of cobalt or cesium for a certain production. Cobalt decays at 12 percent a year, true, and you replenish usually annually or semiannually in the bigger plants; some plants go as long as 2 years. However, if you're talking about cesium and think that you can just buy what you need at a given date and expect that, OK, you're going to have 30 years half life, and you don't have to worry about shipping other cobalt, then what we're talking about is a flat business. We hope these businesses are going to grow; therefore you will have to replenish your sources of cesium. Also, there are some problems that have to be addressed before cesium is really comparable to cobalt's use. When we talk about 10 cents a curie with cesium, you're talking about a factor of 7 to 1 to produce the same throughput. However, a customer who is buying cesium will probably have to have a considerable amount of product holdup in his facility to efficiently utilize that cesium. There is a possible problem there.

When you talk about 10 cents a curie, you're up to 70 cents a curie—they're quoting a dollar a curie for cobalt today—I would say that that is not a factor at this time. Cobalt is going for less than a dollar a curie today. However, they will be competitive if the problems can be resolved.

Getting on to food, in Canada there are three applications that we are currently addressing. Our Government has looked very favorably on the recommendations made by the Codex Alimentarius. We have started our poultry efficacy testing; as a matter of fact, we started that 2 weeks ago. Poultry was approved in 1973. The efficacy testing is the work that you have to do prior to working on a commercial basis; that is, you have to prove on a commercial scale that you can get the same effect in the food as you would get in a pilot scale or a laboratory scale. With respect to poultry, Canada is very concerned about salmonella, and we expect that you will see the commercialization of poultry within the next year, something that the United States, our neighbors, can watch and then use very nicely.

With respect to fish, extension of shelf life of fish, Canada has a problem because the population on the east coast is very sparse compared to the fishing grounds around New York and Boston, so we export a lot of fish and some of the trawlers are out as much as 10 days. We feel that we can extend this shelf life. We have just concluded a market study trial, and now they are going into the efficacy testing. The market trials were very favorable.

And, of course, the third area we are looking into right now is processing of spices, which are all approved and I believe it's just a question of time before we get into these areas of work.

I'd like to say a word about the public, how they look at this. I certainly have spent as much as 4 or 5 hours on public television where there have been open phone lines, and I can only say that the experience that I've had was very positive. One caution that I think all scientists should pay attention to is that the public would like to know; they would like to be informed. They feel that they can think things out. They don't want the Big Brother image saying, "Don't worry; we'll take care of you." They want to be informed so they can think and make their own decisions, and this came through very strongly.

I think that would conclude, basically, what I had to say, Madam Chairman, and I thank you for the opportunity to address the meeting.

[The prepared statement of Mr. Fraser follows:]

STATEMENT OF MR. FRANK FRASER
ATOMIC ENERGY OF CANADA LIMITED

INTRODUCTION

I want to talk to you today about Cobalt-60 supply, demand and price.

The business of supplying sealed radioactive sources for gamma radiation processing cannot be approached lightly. It is estimated that up to 45% of all gamma sterilizable medical disposable products are currently being sterilized with this process, and also, the irradiation preservation of food on an international commercial basis shows great promise. The benefits of this technology are already being felt by hundreds of millions of people.

Medical disposable manufacturers who are using gamma sterilization have already invested large amounts of capital in testing and developing compatible materials.

We, as an industry, are continually addressing the public concern of nuclear processes, the shipment of radioactive material and its disposal. In this paper I will explore the various aspects of the commitment and trust in the future, that we in the Gamma Processing Industry must establish and maintain.

SUPPLY

Since AECL's Second Gamma Processing Seminar in May of 1980 we have shipped 46 million curies of Cobalt-60. The shipment of this 46 million curies required 256 F-168 transport containers and was delivered to 26 countries throughout the world.

In this same period of time we have designed, manufactured and installed 22 new gamma processing plants with several more currently awaiting installation. The Cobalt-60 capacity of these new plants is 55 million curies. The average loading of these facilities to date is approximately 27% of their licensed capacity. This compares with some 50 plants installed in the 16 years between 1964, when we installed our first unit designed for Ethicon Inc. to sterilize sutures, and our last Seminar in 1980.

In reviewing the overall Cobalt-60 supply situation for industrial irradiator use, AECL has shipped a total of 118 million curies since the commissioning of our first Cobalt-60 therapy unit in October 1951. The use of this cobalt can be categorized into three major areas. The first for cancer therapy, the second for self-contained research irradiators, and the third and largest application for the sterilization of medical disposable products. Of the total Cobalt-60 shipped to date, 13 million curies has been shipped for cancer therapy equipment, 99 million curies for industrial irradiators and the balance for research. One can conclude from the above that Gamma Radiation Processing is well established and is experiencing excellent growth. As a matter of fact, close to 50% of the total curies shipped for industrial purposes has been dispatched since our last Seminar in May 1980.

We have reviewed the past Cobalt-60 supply situation and I have taken the liberty to highlight a few statistics to emphasize the magnitude of this business.

What about the future supply of Cobalt-60? All the cobalt referred to in this paper was produced at AECL's NRU and NRX research reactors and at Ontario Hydro's Pickering A Nuclear Power Generating Station where there are four reactor units in operation. Currently, 80% to 90% of our Cobalt-60 supply is produced by Ontario Hydro.

The potential future supply of our energy source will primarily be from three new electrical power generating stations scheduled to be in operation by 1990. Two of these stations, Bruce "B" and Pickering "B" will be in operation within the next year with the Darlington station scheduled for start-up in the late 1980's.

The Bruce "B" station will operate four reactors, each with a nominal Cobalt-60 production capacity of 5 million curies. Pickering B will bring on stream three reactors with a nominal combined Cobalt-60 production capacity of 10 million curies. The Darlington station will operate four units similar to Bruce B and will have a total nominal capacity of 20 million curies.

In total, the 11 new reactors described, along with the four existing Pickering A units, have a potential annual Cobalt-60 production capacity of 63 million curies.

In addition to this, we plan to make available 3 to 7 million curies from our research reactors and other sources.

Ontario Hydro, who produce the major portion of the world's Cobalt-60 supply, irradiate the cobalt in the reactor adjuster rod positions. The number and orientation of cobalt targets contained in each adjuster rod is specifically designed to minimize fuel burn-up and to produce Cobalt-60 efficiently. An upside to the supply of Cobalt-60 from Ontario Hydro is that there is a possibility to produce in the order of 30% more cobalt in each reactor. However, the incremental cost of this cobalt will be significantly higher than the cobalt produced under the current and planned optimum conditions.

DEMAND

The demand for Cobalt-60 in the past has been substantially from the medical disposable products manufacturers. Today, 60 million curies are installed in your facilities processing goods. We estimate this number to increase to 200 million in the next ten years at which time we believe that more than 60% of all gamma sterilizable medical disposable products will be radiation sterilized. If our forecasts are correct it means that we, in AECL, will have to ship over 300 million curies.

Throughout this period we expect two new gamma processing applications to emerge, namely, food preservation and waste treatment. To satisfy the ten year Cobalt-60 demand we will require 43 million curies for food processing and 45 million curies for waste treatment. Therefore, we see the total demand for Cobalt-60 over the next ten years to be in the order of 400 million curies. The supply of Cobalt-60 for this same period based on the nominal supply from Ontario Hydro, AECL and from other sources approximates 435 million curies. If we add to this the potential of increasing Ontario Hydro's production by 30%, the available Cobalt-60 for this period is estimated to be 550 million curies. Both of these figures meet the market demand. However, I must point out that while we are confident in the overall number presented we have not as yet found the formula to predict the rate at which this industry will grow. We may find for short periods supply lagging rather than leading demand resulting in longer than normal deliveries.

PRICE

To convert all new reactor units for cobalt production is estimated to cost 40 million dollars of which AECL has already committed 50%. The remaining 50% will be committed when demand forecasts are confirmed. In addition to this, the expansion of our cobalt processing facilities to accommodate the encapsulation, measurement and shipment of up to 80 million curies annually will cost 15 million dollars over the next 5 years.

From an operating standpoint, our major expenses are for Cobalt-60 inventory and decay. The purchase of cobalt from Ontario Hydro is not on a curie basis. AECL pays for neutrons from the day the Cobalt-59 targets are installed in a given reactor.

In order to produce Cobalt-60 with suitable specific activities it must remain in the reactor from 12 to 18 months. Add another 3 to 6 months to remove the sources from the reactor, ship to AECL and encapsulate, and then ship to the user, results in substantial amounts of money tied up for periods of 15 to 24 months.

Cobalt-60 decay is not negotiable and we, as well as you, must live with it. To date we have lost through decay 16% of the total 118 million curies Cobalt-60 available for shipment. In addition to the previously discussed capital and operating expenses we must include salaries as well as shipping container design, manufacture and maintenance. The containers which we use to ship cobalt to your facilities cost in excess of $35,000 each.

The integrity of AECL source pencils is vital to our operation. Today we have over ten thousand C-188 source pencils in service. Many of these have been in service since 1964. To date we have not had a single failure. This was not achieved by chance. Years of development work including that necessary to successfully encapsulate the start-up neutron sources for the Nautilus, United States' first nuclear powered submarine, and continuous metallurgical inspection of source pencils specifically taken out of field service for testing, support this technology. Much of this expertise will become evident when you visit our Cobalt encapsulation facilities later this week.

Cobalt-60 pricing is primarily based on reactor fuel charges associated with its production. Because of long-term contract commitments which assure the supply of fuel for Ontario Hydro Candu reactors, we will be faced with annual price increases which may be higher than our inflation rate. However, today we do not on the average expect increases to exceed 10%.

There has been an annual increase in Cobalt-60 pricing of approximately 10% over the past few years due primarily to rapidly increasing reactor fuel costs. However, offsetting this price increase we have seen, as a result of the implementation of new sterility control concepts, an overall reduction in dose and corresponding Cobalt-60 requirements as high as 50%.

From the above one can conclude that Cobalt-60 requirements, which represent 25% to 45% of overall sterilization cost at a dose of 2.5 megarads, will be considerably reduced. A user requiring 1 million curies to process at a dose of 2.5 megarads requires only 600,000 curies at a dose of 1.5 megarads. At a dollar per curie this represents a saving of $400,000 for the initial source and an annual saving in replenishment costs of $73,800. A reduction of 40% in Cobalt-60 costs initially and annually can be realized as a result of dose reduction.

This may not apply to many of our British and European customers who currently use a sterilization dose of 2.5 megarads. There is, however, considerable debate on this matter which could lead to a reduction of sterilizing dose.

CONCLUSION

A supplier does not enter this business looking for a quick return. The plan for converting the new Bruce, Pickering and Darlington stations, a total of eleven reactors with a primary purpose to produce electrical power, was made several years ago. We, as you, believe in Gamma Processing and together have built an exciting industry. This industry initially founded on cancer therapy treatment evolved into the sterilization of medical disposable products and is now on the brink of branching out into a new and long anticipated application - the preservation of food. If successful, we can all say we had a part in developing and commercializing a technology which will be of benefit to all mankind.

Finally, AECL's message to you is that we believe you've made the right decision to go with Cobalt-60 and that we will strive to meet all of your Cobalt-60 requirements to the best of our ability at a price which is competitive with alternative sterilizing and preserving methods.

Mrs. LLOYD. Well, thank you very much, Mr. Fraser, for your testimony.

Mr. Chin, would you proceed?

STATEMENT OF ALLAN CHIN, PRESIDENT, RADIATION STERILIZERS, INC.

Mr. CHIN. Madam Chairman, I am president of Radiation Sterilizers, Inc., a California-based company which owns and operates several large-scale gamma facilities to provide contract sterilization services to manufacturers of disposable medical devices. The company also markets turnkey gamma facilities for large-scale industrial users.

I have been active in the design and operation of gamma sterilization facilities for 15 years, and I formed this company in 1978 to provide the medical device industry with a safe alternative sterilization process to ethylene oxide gas, which has been proven to be both mutagenic and carcinogenic.

My technical qualifications include undergraduate and graduate degrees in chemical engineering from MIT. I am also a licensed professional engineer in both chemical and nuclear engineering.

As we have heard, by far, the largest single use of gamma irradiation today is for the sterilization of medical disposable products. Most of the growth in this application has taken place during the last 5 years. As recently as 7 years ago only about 5 percent of the medical industry was using gamma sterilization for their products. The large majority of the industry was using a gas fumigation process employing ethylene oxide gas. This process was in favor because it was cheap, functional, and apparently safe.

However, in 1977 the EPA released the results of toxicity tests which showed that ethylene oxide was mutagenic. Additional tests performed by both industry and regulatory agencies provided strong evidence that ethylene oxide was also a carcinogen.

At this time, many large medical product manufacturers and companies, such as RSI, recognized the hazards of ethylene oxide and began to evaluate alternative processes. Radiation emerged as the only viable solution. Fortunately, the vast amounts of prior research undertaken during earlier food irradiation programs provided the technical basis for the design of medical product irradiators.

In concert with this effort, as more radiation capacity came on line, the regulatory agencies were able to consider tighter regulations and restrictions on the use of this hazardous material. As a result of these efforts, the use of gamma sterilization for medical products has grown to 35 to 40 percent.

The increased usage of gamma sterilization is projected to continue, and industry sterilization usage of 75 to 80 percent are anticipated by 1987. The safety and reliability aspects of this process have been well established and accepted by the medical industry. As an additional bonus, the process has proven to be more cost effective.

The exclusive source for gamma rays for this application has been the radioisotope cobalt-60. This isotope is manmade in nuclear power reactors. In a sense, it is a form of nuclear waste. The virtual sole source for the cobalt-60 is the Atomic Energy of Canada, Ltd.

Recently, the DOE initiated a program to produce a small amount of cobalt-60 in its Idaho Falls reactors for the U.S. industry. The total produced amounts to less than a few percent of the total industry requirement, and therefore is not a significant factor. The industry desperately needs a second source of gamma rays. Although the Government has the capability to produce large amounts of cobalt-60, the DOE apparently has more critical uses for its neutrons, and has indicated that its cobalt-60 production will not be increased.

Currently, the Atomic Energy of Canada, Ltd., is not able to provide the medical industry's needs for cobalt-60. This has generated very serious problems for RSI as well as the rest of the medical industry. Any other application for gamma rays, such as food irradiation, will only serve to compound and exacerbate this problem.

The only other viable source of gamma rays is the isotope cesium-137. This isotope is a waste byproduct which is being continuously generated in the Nation's nuclear power reactors. The cesium-137 represents one of the major radioactive constituents in our nuclear waste.

The DOE Recovery and Reutilization Program was undertaken to help solve the problem of the Nation's radioactive waste management. I strongly support this program, and perceive it as a possible solution to the nuclear waste problem and also as a second source of gamma rays.

The DOE, at considerable expense, has successfully demonstrated that the recovery of cesium-137 is viable. Approximately 80 million curies of cesium-137 have been separated and encapsulated in the DOE facilities in Hanford, WA. This material is not available to industry because of NRC restrictions. This material is currently wasting away in storage pools.

I have reviewed much of the data pertaining to the waste encapsulation and storage facility capsules, commonly referred to as WESF capsules, and I have also had lengthy discussions with the scientists at Battelle Pacific Northwest Laboratories and Rockwell International regarding the safe usage of these capsules in industrial facilities such as RSI operates.

My conclusion is that there are no substantive technical reasons why the WESF capsule cannot and should not be used in properly designed gamma irradiators. RSI has applied to the NRC for approval to use the WESF capsules in its facilities; through the joint efforts and cooperation of the NRC and DOE, it is my fervent hope that this approval will be granted in the very near future, and that this application will represent the first commercial utilization of the Nation's nuclear waste byproducts. I certainly hope I will not have to wait the 6 months or more for tests to be run, since there are no reasons to believe that the results will be negative.

In addition to this, the Department of Energy has expressed a willingness to run an ongoing annual testing program on the specific WESF capsules used in the facilities.

The first large scale uses of radiation for sterilization were projected for the food industry. Due to a variety of reasons, these have never reached fruition. However, the massive amounts of research undertaken during the 1940's and 1950's on food irradiation have provided the groundwork for the successful use of radiation in the medical field in the 1960's.

The current state of the art in large scale equipment technology has been developed for the medical industry. Fortunately, this technology can be beneficially applied directly to the food industry.

There is certainly a close parallel between the medical and food industries regarding the potential usage of radiation as a means of microbial control. The medical industry had its ethylene oxide, and the food industry has its ethylene dibromide. Both are gas fumigation processes which have enjoyed many years of unchallenged usage until regulatory agencies have determined that they pose a serious health hazard to people. In both instances, radiation has emerged as the most viable, safe alternative.

In any discussion on radiation it should be recognized that there are two types of radiation which can be used. Up until now I have discussed primarily gamma radiation because that is the predominant choice in the medical industry. The other form of radiation is beta, or electron radiation, generated from high voltage machines.

The major differences between these two forms of radiation will govern their application. Gamma processing is characterized by high penetration and low dose rates, whereas electron beam processing is characterized by low penetration and high dose rates.

In the medical industry, the products are generally packaged into large cartons. Gamma processing, because of its high penetration, is the method of choice. In the food industry, cartonized packaging will require gamma processing. However, if individual food items are treated, electron beam processing will certainly be possible. The use of the electron beam in food irradiation will certainly have a higher potential than it did in the medical industry.

The safety and wholesomeness aspects of irradiated foods have been satisfactorily addressed by many agencies. Most members of the radiation community are in general agreement that radiation can be applied safely and beneficially to many food products to preserve and extend their shelf life.

I would like to summarize our position as follows.

One, food preservation is a safe, beneficial use of radiation.

Two, the technology is currently available to develop large-scale food irradiators.

Three, the dependence on a sole source for an adequate supply of gamma rays is a very critical industry concern.

Four, the approval and development of a continuing source of cesium by the DOE is necessary for food irradiation to become a reality.

Five, consumer education and acceptance will certainly greatly influence the rate of growth of this application.

And finally, sixth, food irradiation will ultimately be used worldwide to extend the utilization of our food crops.

Madam Chair, thank you for this opportunity, and I certainly appreciate your interest in this subject. I will be pleased to answer any questions that you have.

[The prepared statement of Mr. Chin follows:]

STATEMENT OF ALLAN CHIN

Mr. Chairman and Members of the Subcommittee, my name is Allan Chin. I am president and Chief Executive Officer of Radiation Sterilizers, Inc., a California-based company which owns and operates several large scale gamma facilities to provide contract sterilization services to manufacturers of disposable medical devices. The Company also markets turn-key gamma sterilization facilities for large scale industrial users.

I have been active in the design and operation of gamma sterilization facilities for fifteen years, and I formed Radiation Sterilizers in 1978 to provide the medical device industry with a safe alternative sterilization process to ethylene oxide gas, which has been proven to be both mutagenic and carcinogenic.

My technical qualifications include undergraduate and graduate degrees in chemical engineering from M.I.T. I am also a licensed professional engineer in both Chemical and Nuclear Engineering.

By far, the largest single use of gamma irradiation today is for the sterilization of disposable medical products. Most of the growth in this application has taken place during the last five years. As recently as seven years ago, only five percent of the medical industry was using gamma sterilization for their products.

The large majority of the industry was using a gas fumigation process employing ethylene oxide gas. This process was in favor because it was cheap, functional, and apparently safe.

In 1977, the EPA released the results of toxicity tests which showed that ethylene oxide was mutagenic. Additional tests performed both by industry and regulatory agencies provided strong evidence that ethylene exide was also a carcinogen.

Many large medical product manufacturers and companies, such as RSI, recognized the hazards of ethylene oxide and began to evaluate alternative processes. Radiation emerged as the only viable solution. Fortunately the vast amounts of prior research undertaken during earlier food irradiation programs provided the technical basis for the design of medical product irradiators. In concert with this effort, as more radiation capacity came on line, the regulatory agencies were able to consider tighter regulations and restrictions on the use of this hazardous material. As a result of these efforts, the use of gamma sterilization for medical product sterilization today has grown to 35–40%.

The increased usage of gamma sterilization is projected to continue, and industry sterilization usage levels of 75–80% are anticipated by 1987. The safety and reliability aspects of this process have been well established and accepted by the medical industry. As an additional bonus, the process has proven to be more cost effective.

The exclusive source for gamma rays for this application has been the radioisotope cobalt-60. This isotope is man-made in nuclear power reactors. In a sense, it is a form of nuclear waste. The virtual sole source of cobalt-60 has been from the Atomic Energy of Canada Ltd. (AECL).

Recently, the D.O.E. initiated a program to produce a small amount of cobalt-60 in its Idaho Falls reactors for U.S. industry. The total produced amounts to less than a few percent of the total requirement.

The industry desperately needs a second source of gamma rays. Although the government has the capability to produce large amounts of cobalt-60, the D.O.E. apparently has more critical uses for its neutrons, and has indicated that its cobalt-60 production will not be increased.

Currently the AECL is not able to provide the medical industry's needs for cobalt-60. This has generated very serious problems for RSI as well as the rest of the medical industry. Any other application for gamma rays, such as food irradiation, will only serve to compound this problem.

The only other viable source of gamma rays is the isotope cesium-137. This isotope is a waste by-product which is being continuously generated in the nation's nuclear power reactors. The cesium-137 represents the major radioactive constituent on our nuclear waste.

The D.O.E. Recovery and Re-Utilization program was undertaken to help solve the problem of the nation's radioactive waste. I strongly support this program, and perceive it as a solution to both the nuclear waste problem and the second source of gamma rays.

The D.O.E., at considerable expense, has successfully demonstrated that the recovery of cesium-137 is viable. Approximately 80 million curies of cesium-137 have been separated and encapsulated in the D.O.E. facilities in Hanford, WA. This material is not available to industry because of N.R.C. restrictions. This material is currently wasting away in storage pools.

I have reviewed most of the data pertaining to the Waste Encapsulation and Storage Facility capsules (WESF). I have also had lengthy discussions with the scientists at Batelle Pacific Northwest Laboratories and Rockwell International.

My conclusions on the WESF capsule are that there are no substantive technical reasons why they cannot and should not be used in properly designed gamma irradiators. RSI has applied to the N.R.C. for approval to use the WESF capsules in its facilities. Through the joint efforts and cooperation of the N.R.C. and D.O.E., it is my hope that this approval will be granted in the very near future, and that this application will represent the first commercial utilizataion of the nation's nuclear waste by-products.

The first large scale uses of radiation for sterilization were projected for the food industry. Due to a variety of reasons these never reached fruition. However, the massive amounts of research undertaken during the 40's and 50's on food radiation, provided the groundwork for the successful use of radiation in the medical field in the 60's.

The current state of the art in large scale equipment technology has been developed for the medical industry. Fortunately, this technology can be beneficially applied directly to the food industry.

There is certainly a close parallel between the medical and food industries regarding the potential usage of radiation as a means of microbial control. The medical industry had its ethylene oxide, and the food industry has its ethylene dibromide. Both processes enjoyed many years of un-challenged usage until regulatory agencies determined they posed a serious health hazard to people. In both instances, radiation has emerged as the most viable, safe alternative.

In any discussion on radiation, it should be recognized that there are two types of radiation which can be used. I have discussed primarily gamma radiation because that is the predominant choice in the medical industry.

The other form of radiation is beta or electron radiation generated from high voltage machines.

The major differences between the two forms of radiation define their application. Gamma processing is characterized by high penetration and low dose rates. Conversely, electron beam proceessing is characterized by low penetration and high dose rates.

In the medical industry, the products are generally packaged into large cartons. Gamma processing because of its high penetration is the method of choice.

In the food industry, cartonized packaging will require gamma processing. If individual food items are treated, electron beam processing will be possible. The use of the electron beam in food irradiation will have a higher potential usage than the medical industry.

The safety and wholesomeness aspects of irradiated foods have been satisfactorily addressed by many agencies. All members of the radiation community are in general agreement that radiation can be applied safely and beneficially to many food products to preserve and extend their shelf life.

Our position can be summarized as follows:

1. Food preservation is a safe, beneficial use of radiation.
2. The technology is currently available to develop large scale food irradiators.
3. The dependence on a sole source for an adequate supply of gamma rays is a very large industry concern.
4. The approval and development of a continuing source of cesium by the D.O.E. is necessary for food irradiation to become a reality.
5. Consumer education and acceptance will greatly influence the rate of growth of this application.
6. Food irradiation will ultimately be used worldwide to extend the utilization of our food crops.

Mr. Chairman and members of this committee, thank you for this opportunity to make these statements, and I will be pleased to answer any questions you may have.

Mrs. LLOYD. Well, thank you very much, Mr. Chin. I was going over my list of questions that I was going to ask both of you, and it seems that you have covered all the questions I was going to ask you. I want to thank you for your very comprehensive statements, but I am sure there are other members of this committee who are not here today that would like to submit questions to you in writing, but your answers will be included in the record of this hearing.

Thank you again, and we look forward to hearing from you again. Thank all of the participants.

If there is no further business, the committee stands adjourned.

[Whereupon, at 12:30 p.m., the subcommittee recessed, to reconvene at the call of the Chair.]

APPENDIX

Battelle
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Telephone (509) 375-2419
Telex 15-2874

August 24, 1984

Ms. Marilyn Lloyd, Chairman
Subcommittee on Energy
Research and Production
B-374 Rayburn HOB
Washington, DC 20515

Attention: Nancy Jeffery

Dear Madam Chairman:

Following are corrections or changes that I would like to incorporate into the transcript of my testimony given before the Subcommittee on Energy Research and Production on July 26, 1984. A xerox copy of the transcript showing these changes in red is enclosed.

Page 115, line 2214

Note of explanation: When one receives a tooth or chest x-ray, he is subjected to the x-ray and receives a small radiation dose. When one consumes irradiated food, he receives no dose at all because the food is in no way radioactive. Therefore, the comparison is not a valid one.

Congressman Morrison earlier compared the effect on the food with that of a human receiving an x-ray. In this case, the food does not become radioactive any more than the person does. This comparison is valid and is valuable to helping people understand the effect.

Page 116, line 2247

Line should read: proposed by the USDA for approval of irradiation of food.

Page 117, lines 2255, 2256, 2257

Lines should read: is the emergence of adults. You will notice that with the exception of one fly that seems to be a result of
cross-contamination, we have no emergence of adults at all,

Page 117, line 2263

Line should read: difficult to kill in apples under low temperature

Page 117, lines 2269, 2270, 2271

Lines should read: meet quarantine requirements with codling moth in both the non-diapausing, or active stage, and the diapausing, or
dormant stage.

Page 118, lines 2281 and 2282

Lines should read: as a by-product of Defense Nuclear Fuels. We have 77 megacuries--77 million curies--of material already

Page 118, lines 2290 and 2291

Lines should read: come from future PUREX work, and that would bring the total number of irradiators up to 12. The Savannah River waste, which is

Page 119, line 2311

Line should read: markedly and exceed what we now have.

Page 119, lines 2326, 2327, 2328

Lines should read: bottom, in red, is cesium and barium, which is
a short-lived daughter product of cesium; and when
you remove cesium, you also remove the barium daughter. (Delete It has)

Page 120, line 2329

Line should read: Approximately half of the total heat is generated by

Page 120, line 2334

Line should read: producers and remote power generation; it

Page 120, line 2353

Line should read: Number one, I think there needs to be continued support

Page 121, line 2362

ago--or started to be produced--and the main purpose then was

Page 123, line 2419

Line should read: differences in design that will be required, I certainly

Page 123, line 2421

Line should read: development of this process and we should proceed

If you have any questions concerning the above corrections, please call me at (509)375-2419.

Sincerely,

Garth L Tingey

Garth L. Tingey, Technical Leader
Ceramics Technology and Nuclear
Byproducts Section

PREHEARING QUESTIONS AND ANSWERS
RELATING TO THE

JULY 26, 1984, HEARING
BEFORE THE

SUBCOMMITTEE ON ENERGY RESEARCH AND PRODUCTION
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

WITNESS:
DR. F. CHARLES GILBERT
DEPUTY ASSISTANT SECRETARY FOR NUCLEAR MATERIALS
DEFENSE PROGRAMS
DEPARTMENT OF ENERGY

Question

What is the status of Federal and private R&D activities in the development of irradiation technology?

Answer

The present status of the Department of Energy (DOE) research and development activities was covered in detail in my testimony. It can be summarized as a cooperative program with the U.S. Department of Agriculture, the Agency for International Development, universities, the National Pork Producers Council, and food and grower associations in performing irradiation experimentations and designing and constructing demonstration food irradiators. In addition, the State Department has requested that DOE make available its R&D findings for both food irradiation and tritium airfield lights to the member nations of the Nuclear Non-proliferation Treaty.

Question

To what extent has irradiation technology been developed and commercialized domestically and in what areas of application?

Answer

In non-food industries, irradiation has developed significantly domestically; e.g., in the medical supply industry in lieu of ethylene oxide, which has been used in the past for sterilization. Today over 30 percent of the medical supplies are irradiated. It will grow to greater than 40 percent when several irradiators now under construction are completed. It is believed that by the year 2000 the percentage will be even larger.

Irradiation is also used in polymerizing plastics and rubber and in deposition bonding of paper and wood.

Question

What are the functional differences between the irradiation of food stuffs and non-food items?

Answer

In the non-food items, while there is a minimum dose required to accomplish a desired objective (i.e., to sterilize or polymerize, etc.), the maximum dose may be quite flexible. Food, on the other hand, would be irradiated to tight minimum/maximum dose limits. It is this functional difference for food irradiation that forms the basis for government research and development to ensure safety, process, and quality control.

Question

How do you contrast our domestic achievements in this area with those of the international community?

Answer

While the United States has pioneered the field of food irradiation technology, in recent years several nations have expanded their program beyond ours. Other witnesses, particularly the Food and Drug Administration (FDA), can furnish more details on these international achievements.

Question

What are the major obstacles, institutional and otherwise, impeding the development of food irradiation technology?

Answer

I believe, and I know others share this belief also, that the greatest institutional impediment to the food irradiation program has been the lack of an irradiation regulation. Once we have a limit (e.g., 100 kilorads) then we can properly conduct our efficacy and phytotoxicity testing. In addition, the fact that food irradiation has been designated an additive rather than a process has been an impediment to food irradiation technology. This in turn forms the basis of an adverse public attitude. For years we have been exposing the public to ethylene dibromide (EDB), a deadly chemical, and now are replacing it with something "nuclear." Private industry must do a credible job of public education regarding the benefits and risks of the food processing technologies.

Question

What are the major incentives for the further development of irradiation technology for the food industry?

Answer

We would defer to potential users to define what incentives there are to further development of irradiation technology.

Question

What problems currently exist or are anticipated regarding the availability of radioisotope source materials?

Answer

As DOE is primarily concerned with cesium, we will focus on the problems that exist regarding its availability. They are:

1. The need to conclude the cesium-137 capsule-irradiator licensing process at NRC on the current capsule design.
2. The need to complete the fabrication and licensing of a cost-effective cesium shipping system.
3. The need to complete the ongoing rulemaking process governing the food irradiation process.

We think there may be future problems in the licensing of new cesium fuel forms and capsule designs postulated to improve safety and efficiency.

Question

Is machine-generated irradiation emerging as a realistic near-term option?

Answer

Machine-generated irradiation, when used to irradiate low-density materials, holds great promise as an option. While such radiation does not penetrate as well as photons from cesium or cobalt, it has the potential to augment the isotopes in those low-density materials and thereby reduce demand for cesium and cobalt.

Question

What should the government's role be in exploiting the full potential of food irradiation technology?

Answer

The government's role should be one of providing the availability of gamma sources, defining the parameters critical to irradiation treatment of agricultural commodities, removing regulatory impediments, and encouraging technology transfer with developing countries.

Question

What impact will current legislative and regulatory proposals have on the further development of this technology?

Answer

The impact of H.R. 5605 that would acknowledge irradiation of food as a process rather than a food additive will greatly reduce the time and resources required to implement irradiation as an effective disinfestation process. The Food and Drug Administration proposed rule (Irradiation in the Production, Processing, and Handling of Food, 21 CFR Part 1791) will enable irradiation of fruit and vegetables up to a dose of 100 kilorads. This level should enable the disinfestation of food commodities currently being fumigated.

UNITED STATES DEPARTMENT OF COMMERCE
National Bureau of Standards
[illegible] Gaithersburg, MD 20899
OFFICE OF THE DIRECTOR (Mailing address change only)

July 24, 1984

Honorable Marilyn Lloyd
Chairwoman, Subcommittee on Energy
Research and Production
Committee on Science and Technology
House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

In response to a request by Keith Jansen, Technical Consultant to your Subcommittee, I am enclosing a statement by Dr. William L. McLaughlin of the National Bureau of Standards' Center for Radiation Research for the Record of your July 26 hearing on "The Status of the Technical Infrastructure to Support Domestic Food Irradiation."

Should you require any additional material or information in this regard, I can be reached on 921-2441.

Sincerely,

Esther Cassidy

Esther C. Cassidy
Director
Congressional and Legislative Affairs

Enclosure

STATEMENT OF WILLIAM L. MCLAUGHLIN, CENTER FOR RADIATION RESEARCH, NATIONAL BUREAU OF STANDARDS

Madam Chairwoman and Members of the Subcommittee:

I am pleased to submit this written statement on behalf of the National Bureau of Standards (NBS) for the Subcommittee's hearings on the status of the technical infrastructure to support domestic food irradiation. This statement presents an overview of the technical requirements for measurement quality assurance in food irradiation.

The capability for accurate measurement of radiation dosage (dosimetry) is required in food irradiation for two principal reasons. First, accurate dosimetry will enable industry to comply with proposed federal regulations which impose certain limits on dose. Seondly, it will provide the necessary indication that foods have been given sufficient levels of irradiation dosage which have been prescribed to achieve the desired effect of sterilization, disinfestation, or microbial control.

To ensure that radiation measurements are made with the necessary accuracy, certain measurement quality assurance (MQA) procedures must be employed. These procedures call for periodic measurement performance checks that provide proof of accuracy in radiation dosimetry. These checks, in turn, provide a sound technical basis for recorded measurements which can furnish legal proof of compliance with regulatory limits. Measurement quality assurance also is essential for industry to maintain quality control in food irradiation processes. Good quality control will contribute to public confidence in irradiated foods.

The technical elements of a reliable MQA system include: (1) a system of national radiation measurement standards, such as those maintained by the National Bureau of Standards, to serve as a reference base against which measurements can be compared throughout the food irradiation industry; (2) a set of portable (transfer) radiation measurement standards which can be calibrated against the primary national standards at NBS and then transported to private sector laboratories to calibrate industrial measurement devices and radiation sources or to check the performance of private calibration facilities; (3) a reliable set of industrial radiation measurement instruments that are capable of achieving the appropriate accuracy and whose measurement performances are sufficiently independent of changes in envirnomental factors such as temperature, humidity, pressure, or energy of the radiation being used; and (4) an agreed upon set of routine measurement assurance procedures for using these standards and measurement devices to make periodic performance checks on calibrations and field-level measurements.

The technology for meeting these four requirements is mainly in hand, but a few important improvements are needed. (1) The primary standards maintained at NBS are adequate for the types of radiation proposed for this industry up to energies of two million electron volts (MeV). If higher energy radiation sources (2 to 10 MeV) are used in the future, further development of primary measurement standards for use in that energy region will be necessary. (2) Some portable (transfer) standards are available but research and development should produce new designs that are simpler, more reliable and less expensive. These more cost-effective devices will be important in what is expected to become a highly competitive industry both nationally and internationally. (3) Radiation measurement instruments are presently available for use in food irradiation but they are not so simple, reliable and inexpensive as will be desired for economic reasons. One major need is for small, inexpensive dosimeter devices that can measure radiation doses in-situ, i.e. at various points throughout a large food package to ensure that all portions of the food have received a proper radiation dose. There are promising devices, such as the fiber optic dosimeter, that may serve this purpose if further research and development efforts are made to bring them into commercial usage.

The National Bureau of Standards has assisted in establishing measurement quality assurance systems in several areas of radiation application, including occupational personnel dosimetry, medical radiation diagnostics and therapy, and state radiation control programs. Our experience in establishing these systems has shown greatest success when the measurement assurance procedures are developed on a consensus basis, i.e., when the private sector users of radiation, the standards organizations, and the government agencies are all involved and influential in the design of the procedures. This consensus process ensures that the procedures are technically sound, practical, cost effective, and adequate from a regulatory point of view.

An important need being recognized in the food irradiation field is for a method of determining whether a food sample has been irradiated and to what extent. This will be especially important to ensure that an unlabeled food is not inadevertantly re-irradiated to a level beyond the legal limit. The results of previous research in radiation chemistry suggest that further reseach and development work might permit the identification of certain unique irradiation products whose presence and amounts could be measured and related to the original radiation dosage. This approach appears promising and warrants careful serious consideration.

A more detailed discussion of the technical requirements for measurement quality assurance is given in the attached documents (Attachment A and Attachments 1, 2, and 3).

July 24, 1984

Attachment A

TECHNICAL REQUIREMENTS FOR MEASUREMENT QUALITY ASSURANCE IN FOOD IRRADIATION

by

William L. McLaughlin
Center for Radiation Research
National Bureau of Standards

a. Standardized Radiation Dosimetry: Research and Development

Standardized radiation dosimetry is the chief means of establishing and maintaining quality control in the radiation processing of food. The major technical problems of achieving this quality assurance are addressed in our recent reprint (attachment 1), entitled "Radiation Dosimetry for Quality Control of Food Preservation and Disinfestation" published in Radiation Physics and Chemistry, Vol. 22, pages 21-29, 1983. The summary paragraph of that paper is as follows:

"Improved radiation dosimetry quality control can readily be provided by a joint effort between industrial and national programs. The success already established in industrial radiation sterilization of medical products should, in the next five years, carry over to food processing, as it grows to a large industrial effort. Routine dosimetry systems are not yet fully developed on a mass produced scale for all dose levels and radiation energies used in food processing. Further development is needed especially to fill the void at the lower dose levels (10-10^3 Gy). ESR and lyoluminescence analyses of such substances as amino acids and saccharides are especially promising dosimetry systems for the full dose range of interest in food irradiation, even up to 10^5 Gy. Another highly promising system is a fibre optics device using radiochromic solutions in optical waveguides. These solutions consist of food-equivalent materials and cover the entire dose range of interest in food irradiation (1-10^5 Gy)."

Typical suppliers of candidate dosimeters for food irradiation are listed in Tables 2 and 3 of that publication. Since the time of that article, another promising dosimetry system based on radiation-induced coloration has come under development by Allied Corporation's New Ventures Group in Morristown, New Jersey.

b. Control and Documentation

In addition to such R & D matters, there are the practical considerations of control and documentation of each radiation process. I quote a paragraph from page 229 of our recent Chapter 8 (attachment 2) in Vol. I of Preservation of Food by Ionizing Radiation, edited by Josephson and Peterson and published by CRC Press of Boca Raton, FL. (1982):

"The degree of control of deposited radiation energy and its documentation are determined by: (1) the specification of the allowable dose limits for each product; (2) the requirements of regulatory agencies; and (3) the relative economics in terms of the costs of process monitoring and control vs. the risks of production and release of unacceptable goods. Documentation is achieved by meticulous data keeping and evidence of fail-proof product inventory."

Reliable dosimetry data keeping includes, of course, maintaining scheduled calibrations of routine dose measurement devices through a formal centralized measurement quality assuance program. For this purpose in the U.S., the National Bureau of Standards provides a well-established Calibration and Measurement Service (Item 8.6) "Dosimetry for High-Dose Applications" (see the appropriate section of attachment 3, Appendix from NBS Special Publication, 250 May 1984). This service is suited to food irradiation dosimetry standardization and quality control. A new NBS effort is planned for developing special standardized dosimeter materials which, if successful, will become available to food irradiation industries as Standard Reference Materials for improving process control and documentation.

Attachment 1

Radiation Physics Chemistry Vol. 22 No. 1/2 pp. 21-29, 1983
Printed in Great Britain

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RADIATION DOSIMETRY FOR QUALITY CONTROL OF FOOD PRESERVATION AND DISINFESTATION

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ABSTRACT

In the use of x and gamma rays and scanned electron beams to extend the shelf life of food by delay of sprouting and ripening, killing of microbes, and control of insect population, quality assurance is provided by standardized radiation dosimetry. By strategic placement of calibrated dosimeters that are sufficiently stable and reproducible, it is possible to monitor minimum and maximum radiation absorbed dose levels and dose uniformity for a given processed foodstuff. The dosimetry procedure is especially important in the commissioning of a process and in making adjustments of process parameters (e.g. conveyor speed) to meet changes that occur in product and source parameters (e.g. bulk density and radiation spectrum). Routine dosimetry methods and certain corrections of dosimetry data may be selected for the radiations used in typical food processes.

In the use of ionizing radiation (e.g. ^{60}Co or ^{137}Cs gamma rays; accelerator electron beams; x rays) to disinfest or prolong the shelf life of large volumes of foodstuffs, accurate and reproducible radiation measurement (dosimetry) plays a key role. The main purpose of dosimetry is to supply cheap and reliable quality control.

The pertinent radiation quantity is radiation absorbed dose*, which is divided into three main ranges, depending on how current regulations are written:

---

*Absorbed dose (D_i) is defined as the radiation energy (E) absorbed per unit mass (m_i) of the absorbing material (i): $D_i = \Delta E/\Delta m_i$. The special named SI unit of absorbed dose is the gray: 1 Gy = 1 joule per kilogram, and 1 Gy is the same as 100 rad, in terms of the older unit.

$< 10^3$ Gy (< 100 krad)	proposed low dose region for foods, not requiring regulation in the US (FDA, 1982).
10^3-10^4 Gy (0.1-1 Mrad)	medium dose region up to 10 kGy proposed for foods, not requiring regulation (International Joint Expert Committee of FAO/WHO/IAEA, 1981).
$> 10^4$ Gy (> 1 Mrad)	high dose region for foods subject to regulations and thorough clearance procedures.

Synopsis of dose ranges for various categories of radiation processing of food are given in Table 1.

TABLE 1

APPROXIMATE DOSE RANGES FOR FOOD PRESERVATION AND DISINFESTATION

	Dose range (kGy)
* potatoes, onions (sprouting inhibition)	0.03 - 0.12
* seeds, flours, fruits (insect disinfestation)	0.2 - 0.8
* insect polulation control	0.05 - 1.0
* meats (parasite disinfestation)	0.1 - 3.0
* perishable fruits, vegetables, meat, poultry, fish (reduce spoilage floura and parasites)	0.5 - 10
* frozen meats, poultry, eggs, animal feeds (reduce pathogenic microbes)	3.0 - 10
* dry foods, spices, starch, enzymes (eliminate pathogens)	3.0 - 20
* meats, poultry, fish (sterilization, including viruses and radiation-resistant microorganisms)	25 - 60

It should be pointed out that although the US Food and Drug Administration has recently proposed rule making that would relax regulations for foods irradiated with doses < 1 kGy, the food processor aims to control deligently the process by administering all radiation doses with certain prescribed limits of uncertainty and within limits of uniformity, depending on the foodstuff and the process [1-3]. The constraints are obvious, in that the successful process requires sufficient irradiation throughout the product to prevent latent re-infestation, spoilage, insufficient shelf-life extension, etc. It also depends on not over-irradiating, since sterilized insects, for example, may be immobilized against necessary sexual encounters, or the quality and wholesomeness of foods may be impaired by too large a dose. Thus, the values of minimum and maximum dose (D_{min} and D_{max}) and the uniformity ratio ($U = D_{max}/D_{min}$) must be controlled with suitable statistics, and thus, with adequate dosimetry. Moreover this measurement assurance must be maintained for large volumes of foodstuffs in a production irradiation facility.

Examples of suitable dose levels and statistical requirements for individual food irradiation processes are found abundantly in the literature [3-7]. Examples of dosimetry procedures and systems for specific food processing applications are also well documented [8,9] (see Tables 2 and 3).

TABLE 2

DOSIMETERS FOR FOOD IRRADIATION

(Limited availability, requiring special preparation and handling)

Dosimeter Systems	Methods of Analysis	Sample Supplier	Approx.Dose Range (Gy)
amino acids (e.g. alanine)	ESR spectrometry	Gesellschaft für Strahlenforschung Neuherberg Munich, Germany	$1\text{-}10^5$
amino acids or saccharides	lyoluminescence	Department of Biomedical Physics and Bio-Engineering, University of Aberdeen, Scotland	$10\text{-}5\times10^4$
ceric sulfate solution	uv spectrophotometry or electrochemical potentiometry	Atomic Energy of Canada, Ltd. Ottawa, Canada	$10^3\text{-}10^5$
ethanol-chlorobenzene solution	calorimetric titration or HF oscillometry	Ruder Bosković Inst. Zagreb, Yugoslavia or Institute of Isotopes Budapest, Hungary	$10^2\text{-}10^5$
ferrous-sulfate solution (Fricke dosimeter)	uv spectrophotometry	Boris Kidrić Inst. Yugoslavia or National Physical Laboratory, Teddington/Middlesex, UK	$10\text{-}4\times10^2$
ferrous-cupric sulfate solution	uv spectrophotometry	Boris Kidrić Inst. Yugoslavia	$10^3\text{-}3\times10^5$
potassium dichromate solution	uv spectrophotometry or electrochemical potentiometry	National Physical Laboratory Teddington/Middlesex, UK or Australian Atomic Energy Comm. Research Establishment, Sutherland, Australia	$10^3\text{-}10^5$

TABLE 3

DOSIMETERS FOR FOOD IRRADIATION

(Mass-produced, routine systems for large volume use)

Dosimeter Systems	Methods of Analysis	Sample Supplier	Approx. Dose Range (Gy)
dyed polymethyl methacrylate	vis. spectrophotometry	AERE, Harwell, UK or AECL, Ottawa, Canada	10^3-4×10^4
undyed polymethyl-methacrylate	uv spectrophotometry	UK Panel on Electron and Gamma-Ray Dosimetry, Reading, UK	10^3-10^5
cellulose triacetate	uv spectrophotometry	Fuji Film Co., Tokyo, Japan	10^4-4×10^5
lithium borate, lithium fluoride, etc.	thermoluminescence	Harshaw Chemical Co. Solon, OH, USA	$10^{-4}\times10^3$
radiochromic dye films, solutions, papers, fibre optics	vis. spectrophotometry or densitometry	Far West Technology Inc., Goleta, CA, USA	1-10^6

While most of the chemical dosimeters listed in Table 2 provide dose assessments with greater accuracy and precision, the practical systems of Table 3, when properly calibrated, can be highly useful to the radiation processing technologist. In using routine dosimetry for quality control of radiation processes, however, the choice of which dosimetry system should be used for each application depends on answering the following questions:

1. Are acceptable dosimetry systems commercially available on a large scale?
2. Do these systems cover the necessary dose range adequately?
3. Can these systems be accepted by commercial users as sufficiently accurate and reproducible and can they be readily calibrated, that is, are they standardized?
4. Can sources of error and imprecision be satisfactorily controlled or corrected for?
5. To what degree can dose limits and uniformity ratios be assured by current routine dosimetry methods?
6. Are steps being taken to improve the state-of-art in traceability to standards, routine performance, and documentation of food processing dosimetry?
7. Are there alternatives to dosimetry for maintaining quality assurance and routine performance of food processing dosimetry, and can these be properly documented?

At present definitive answers to the questions may be offered:

1. Availability of routine dosimeters

   This is still a serious problem, in that adequate commercially available dosimetry systems are lacking over important regions of the absorbed dose range of interest and ironically, this is especially critical at the lower portion of this dose range (< 1 kGy). (See paragraphs 2 and 6 below).

2. Useful ranges of commercially available dosimeters

   For dosimeters available in large batches, some of the leading candidates are given in Table 3, along with suppliers and useful ranges.

3. Accuracy, reproducibility, and traceability

   Mass-produced dosimeters are not readily available on a routine, large-scale basis for dose assessments at uncertainty limits of < 5 percent. Limits of > 10 percent may, as a rule of thumb, be considered inadequate for most food processing quality control applications.

   As for standardization, there are available national traceability programs in the form of a test and calibration service [10-14]. These services allow commercial and national radiation users to standardize their routine dosimeter performance by traceability to national standards and accurately known doses of radiation. Such programs involve extensive collaboration with international standardization programs such as that sponsored by IAEA [15-16].

4. Systematic error and random uncertainty

   Since it is essential to maintain adequate performance levels in the routine use of dosimeters in large-scale processing, sources of measurement uncertainty must be understood and monitored. Such sources of error and imprecision are as follows:

   a. Dosimeter response functions or calibration curve shape.
   b. Calibration precision limits at various dose levels.
   c. Temperature dependence of dose interpretations, both during and after irradiation.
   d. Other environmental factors (humidity, light, atmosphere, etc.).
   e. The effects of variations in absorbed dose rate or dose fractionation on the response.
   f. Dosimeter stability factors before and after irradiation.
   g. Variations within a dosimeter batch or between batches.
   h. The effect of dosimeter size and displacement of irradiated product of interest by the dosimeter probe material.
   i. Radiation scattering effects on the response of dosimeters placed near interfaces (e.g., dosimeter wall effect or need for cavity-theory corrections).

j. Effect of differences in radiation spectra between calibration and application or during use (e.g., need for compact dosimeters that match the food product in terms of radiation absorption properties).

k. Effect of adverse handling e.g., scratches, finger prints, impurities, on reliability of dose interpretations.

l. Effects of imprecision and error in specific optical absorptivity or in other dosimeter signal readings on dosimetry reproducibility and accuracy.

5. Measurements of dose distributions and dose uniformity

Details for achieving this phase of dosimetry are given in the literature [1,2,8-10,14,17-19]. The usual procedure is to determine positions of D_{min} and D_{max} in a given food being processed and then to place sufficiently accurate dosimeters at strategic locations in enough random food items to get necessary statistical data for an acceptable value of U for a given process. In the case of regulated dose limits, dosimetry plays an important role in establishing legal requirements for quality control of a given process [1,2].

6. Development of improved dosimeters, dosimetry standards, and dosimetry records

This is a constant effort, especially as there are growing needs for improvement. Presently we are seeking new, improved dosimeters for the lower part of the dose range (1 to 100 Gy) [20-27]. Improved standardized photon and electron sources and primary dosimeter standards (e.g. calorimeters and chemical systems) are also being developed. Archival quality dosimeters, that is, ones giving a permanent record of traceable dose interpretation, are still lacking. Desirable properties of transfer dosimeters are listed in Table 4.

TABLE 4

PROPERTIES OF TRANSFER DOSIMETERS	
Reproducibility in Large Batches	
Easily Calibrated	
Stability Ruggedness Portability	Mailability Intercomparability
Energy Independence	
Rate Independence	
Correctable Systematic Errors	

7. Alternative quality control measures

In the routine use of a large radiation source in food processing, once commissioning of that source is complete for a given process and food of a specified bulk density,

> dosimetry can partially be replaced by control of irradiation parameters (e.g. conveyor speed, bulk density, etc.). Dose distribution calculations by computer techniques can also assist in predicting changes in process parameters, although spot checks by calibrated dosimeters are recommended. A strong recommendation is also made to set up periodic calibration schedules (e.g. quarterly, semi-annually, or annually) and to follow recommended process dosimetry protocols [2,8].

In a summary, improved radiation dosimetry quality control can readily be provided by a joint effort between industrial and national programs. The success already established in industrial radiation sterilization of medical products [17,22,28,29] should, in the next five years, carry over to food processing, as it grows to a large industrial effort [30]. Routine dosimetry systems are not yet fully developed on a mass produced scale for all dose levels and radiation energies used in food processing. Further development is needed especially to fill the void at the lower dose levels (10-10^3 Gy). ESR and lyoluminescence analysis of such substances as amino acids and saccharides are especially promising relevant dosimetry systems for the full dose range of interest, even up to 10^5 Gy [23-25,29]. Another highly promising systems is one described in these proceedings, namely, a fibre optics systems using radiochromic solutions in the optical wave guides consisting of food-equivalent materials and covering the entire dose range of interest in food irradiation (1-10^5 Gy) [26,27].

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Chapter 8

DOSIMETRY

W. L. McLaughlin, R. D. Jarrett, Sr., and T. A. Olejnik

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I. INTRODUCTION

Correct procedures for food preservation and quality control in radiation processing depend to a large extent on accurate and reproducible measurements of ionizing radiation quantities and related biological effects. The important quantities are (1) the energy imparted to foodstuffs and their surroundings during the process and (2) the rate at which this energy is deposited. Therefore, the measurement of absorbed dose and dose rate must be accomplished as accurately as possible. Dosimetry is particularly important in the research leading to a given process and the commissioning of that process.

The techniques of dosimetry are now sufficiently established in food irradiation to provide one of the most reliable means of quality control.[1-4] As in the sterilization of medical supplies, some regulatory requirements stipulate that, in the commissioning stage or after a modification of a process or product geometry, adequate dosimetry be provided to ascertain the distribution of dose (D), which within certain minimum and maximum values (D_{min} and D_{max}) gives a sufficiently small value of uniformity, $U = D_{max}/D_{min}$.[4-6] The value of D_{min} is specified as the absorbed dose in the product that, according to experience or practice, is sufficient to achieve the food preservation goal of interest, whether it be sprouting inhibition, ripening delay, disinfestation of grains and fruits, or the elimination of certain forms of microorganisms. The magnitude of this dose for each process is generally determined by extensive food science and microbiological studies. The value of D_{max} is usually specified as the absorbed dose at which the product becomes legally tainted, or above which irradiation would cause spoilage or other loss of value or wholesomeness.

Measurement of absorbed dose sets the radiation parameters for a given radiation process (conveyor speed, product dwell time, size and density, throughput, and machine settings in the case of X-ray and electron-beam facilities).[3,4] Continuous monitoring of the integrated effects of all parameters based on correct dosimetry generally gives an acceptable degree of quality control, in terms of dose and dose uniformity within achievable precision limits. Methods of determining nominal precision limits by replicate dosimetry may be found in the literature.[3,7]

The types of radiation used in food processing include gamma rays of cobalt-60 or cesium-137, X-rays of several MeV to 5 MeV, or accelerated electrons over an energy range of about 0.1 to 10 MeV. Absorbed doses range generally from 10^3 to 7×10^6 rads (10 to 7×10^4 Gy*). Measurements within this range must be made not only with

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[*] The SI derived unit for absorbed dose is the gray (Gy) as defined by the Comité International des Poids et Mesure (CIPM): 1 Gy = 1 J/kg = 100 rad. During the period up to 1986 the existing unit, rad, will be phased out.

precision, but also with accuracy, so that there is reasonable confidence, i.e., statistical assurance, of achieving the desired dose uniformity without exceeding the extreme limits of D_{min} and D_{max} (see Section VI.C.4).

Calculations of the absorbed dose in the product based solely on estimates of the incident radiation flux density, spectra, and radiation absorption properties of the foodstuff and its surroundings are difficult to achieve, except perhaps in the case of highly uniform product, and monodirectional, monoenergetic radiation beams. In general, experimental dosimetry is preferred over calculational methods, because of the intrinsic heterogeneity of the radiation field and the absorbing matter. Calculations, on the other hand, are useful in predicting differences in measured absorbed dose in different materials, since it is relatively simple to apply ratios of photon energy absorption coefficients and electron stopping powers averaged over estimated radiation spectra at the regions of interest (see Section VI.B.1).[3,4]

The dosimetry procedures presently used in food irradiation cover many well-established techniques, the more important of which will be described later (see also Table 1). We must sometimes distinguish between dosimetry problems for electromagnetic radiation (X- and gamma rays) and those for charged-particle radiation (electron beams). We give several important dosimetry methods and guidelines currently in use and also include a number of those having potential for the future. Approaches for minimizing error and imprecision in dose interpretation will be limited to the more widely used methods of dosimetry.

The main sources of inaccuracy are variations of dosimeter response with dose rate, spectral energy, dosimeter batch variations, readout anomalies, instabilities, and environmental fluctuations both during and after irradiation. Instantaneous dose rates, for example, may vary from about 1 rad/sec in the case of X- and gamma rays, to as great as 10^{10} rads/sec in the case of scanned and pulsed electron beams. At the same time, temperature variations and reactive chemical agents occurring in and around the dosimeters may cause systematic errors in dose interpretations. It is also important to be able to convert from the absorbed dose reading in a calibrated dosimeter material to absorbed dose in a food product of interest.

II. MEASUREMENT OF ABSORBED DOSE

The primary aim of dosimetry is to determine the quantity *absorbed dose*, D, at points of interest in a given absorbing medium. This quantity is defined[5] as the incremental energy imparted by radiation to a small volume of matter divided by the mass of that volume element:

$$D = \frac{dE}{dm}$$

Absorbed dose rate, $\dot{D}$, is the rate of energy deposition per unit mass at any given time, t:

$$\dot{D} = \frac{dD}{dt}$$

The measurement methods and systems that may be used in food irradiation applications, i.e., for measuring large doses (kilorads to megarads; tens of grays to tens of kilograys), cover a vast range of procedures and materials. These may be put into three main categories, as given below. Rough dose monitors, such as "go — no go" visual radiation indicators, are not included here and will be considered in Chapter 9. The categories of interest here are

Table I
CHARACTERISTICS OF ROUTINE DOSIMETERS

Dosimeter type	Instrumentation for analysis	Approximate dose range (Mrad)	Approximate precision limits (1σ)	Approximate water equivalence	Stability		Variation between batches
					Before use	After use	
Ceric-cerous sulfate solution	UV spectrophotometry or electrochemical potentiometry	0.2—5	± 2%	No	Yes	Yes	No
Ethanol chlorobenzene	Oscillometric potentiometry	0.1—40	±4%	Yes	Yes	Yes	No
Lyoluminescence							
Saccharides	Integrated	10^{-4}—0.08					
Amino acids	UV and visible	0.001—0.5	±5%	Yes	Yes	No	Yes
Polymers	photometry	0.2—4					
D-alanine	ESR spectroscopy	10^{-4}—10	±2%	Yes	Yes	Yes	No
Lithium fluoride	Thermoluminescence	10^{-6}—0.1	±3%	No	Yes	Yes	Yes
Lithium borate	detection	10^{-6}—0.5	±3%	No	Yes	Yes	Yes
D-glucose	Optical rotation	1—500	±5%	Yes	Yes	No	No
Colorless Perspex	UV spectrophotometry	0.1—5	±3%	Yes	Yes	No	Yes
Red Perspex	Visible spectrophotometry	0.5—5	±3%	Yes	Yes	No	Yes
Amber Perspex	Visible spectrophotometry	0.15—2	±3%	Yes	Yes	No	Yes
Radiochromic liquid solution	Visible spectrophotometry	10^{-3}—1	±2%	Yes	Yes	Yes	Yes
Radiochromic thin film	Visible spectrophotometry	0.1—100	±3%	Yes	Yes	Yes	Yes
Co^{III}-EDTA	UV spectrophotometry	0.01—10	±5%	No	Yes	Yes	Yes
Cellulose triacetate	UV spectrophotometry	1—40	±8%	Yes	Yes	No	Yes
Polyvinyl chloride	UV spectrophotometry	0.5—6	±10%	No	Yes	No	Yes

Primary reference systems — These are defined here as standard systems whose readings are based on the measurement of basic physical quantities, such as ionization current, electric charge, and temperature, or the measurement of radiation chemical yields from standard solutions that are readily available from stock and are reproducible at any time from one laboratory to another. For the purposes of this chapter, primary reference systems are those that do not need calibration against some other standard dosimeter system. In general, where radiations other than high-energy gamma rays and electrons are used and energy dependence is a problem, calorimetry may be the only reference dosimeter that can be considered a primary system.

Routine transfer systems — Some stable dosimetry systems are suitable for mailing and upon analysis show a reproducible signal (e.g., stimulated light output, optical transmission density change, ESR spectrum) as a function of absorbed dose. The radiation response characteristics of these systems (signal vs. dose) need to be calibrated against the standard response of some suitable reference system, because of systematic errors and unexpected differences in response that may occur from one dosimeter supply to another or within a given batch.

Routine in-house systems — There are also moderately unstable systems showing a reproducible signal, which, upon analysis within a facility, can give adequate dose interpretations as long as they are properly calibrated and suitable corrections are made for errors due to instabilities and variations of response from different dosimeter lots or batches.

III. REFERENCE DOSIMETRY SYSTEMS AND PROCEDURES

A. Calorimetric Dosimetry

In general, ionization methods are not suitable for measuring very large absorbed doses, because of saturation effects in ionization chambers,[9,10] although they may sometimes be useful to determine absorbed dose rates in X- or gamma-ray fields. One of the most direct and useful dosimetry methods employed in food irradiation is calorimetry. Calorimetric dosimetry may involve either complex arrangements using adiabatic enclosures containing reference cells and calibration heat sources or relatively simple quasi-adiabatic or bare heat sensors that lose heat to their surroundings exponentially with time. Many of these calorimeters for radiation measurement are treated in detail in the literature[11-17] and will be outlined only briefly here.

One of the most practical simple calorimeters consists of an insulated polystyrene petri dish containing water and a thermistor or thermocouple, which gives a reading of temperature rise in the water due to irradiation.[13,18-20] The petri dish calorimeter is illustrated in Figure 1, with a styrofoam shell being used to insulate the calorimeter against rapid heat losses during and following irradiation. Thus, for a relatively brief electron beam irradiation (<10 min), the assembly may be disconnected from the readout meter, passed through the radiation field with the food product, and the temperature rise measured immediately afterwards. The absorbed dose is then calculated as follows:

$$D = k \times \Delta T$$

where ΔT is the change in temperature of the water in degrees Celsius and k is a constant determined for a particular calorimetric body:

$$k = \frac{(m_i c_i)}{m_1 \times 2.389}$$

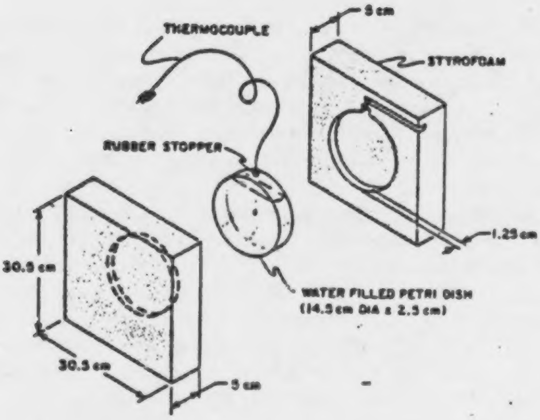

FIGURE 1. Water calorimeter, consisting of water held in a Petri® dish, containing a thermocouple. Thermal insulation is provided by a removable styrofoam jacket.[10,40]

where m_i is the mass of each component contributing to the temperature rise (i.e., water, polystyrene, thermistor wires, etc.) and c_i is the heat capacity of each. The factor, 2.389, represents an energy conversion factor (calories per gram of matter irradiated to a dose of 1.00 Mrad or 10 kGy). Among those discussed here, only this system may be used for on-line applications in the food irradiation, since it is the only one sufficiently insulated and having disconnectable electrical leads. The others are intended mainly for the calibration of other dosimeters for the determination of doses in high-intensity photon or electron fields.

A useful calorimeter design for the calibration of the response of liquid dosimeters is given by Radak et al.[11] A spherical graphite calorimeter is also useful for measuring energy deposition from an isotropic radiation source. This calorimeter is illustrated in Figure 2.[12] The electrical circuits for use and calibration of this calorimeter are shown in Figure 3.

As will be discussed later, the size of the dosimeter may be the main limiting factor in its ability to measure locally the absorbed dose in a medium, particularly if there are gradients of dose over the relatively large size of the petri dish calorimeter, due to buildup, scatter, or attenuation of the radiation. Since calorimeters may be used in a radiation field to calibrate the response of a relatively small or thin routine dosimeter, it may be advantageous to use a thin calorimetric body. This may consist simply of a bare metal disc containing a thermocouple junction,[13] a thermistor bridge,[14] or a sandwich of bare graphite wafers containing small heat sensors, with the thin dosimeter being calibrated by placing it between these separated wafers during irradiation[15] (Figure 4). Another successful design for such purposes is illustrated in Figure 5 and consists of a thin calorimetric body, which can be duplicated geometrically by an adjacent dosimeter assembly.[16,17] When this system passes under a radiation beam in the same irradiation configuration as the calibrating calorimeter, it gives the correct reading of absorbed dose in the dosimeter, as long as suitable corrections are made for (1) heat losses and (2) differences in radiation absorption properties of the two absorbing materials.

A similar design has an exchangeable calibrating calorimetric body matched by a fixed reference calorimetric body, as shown in Figure 6.[18] The calibration is achieved

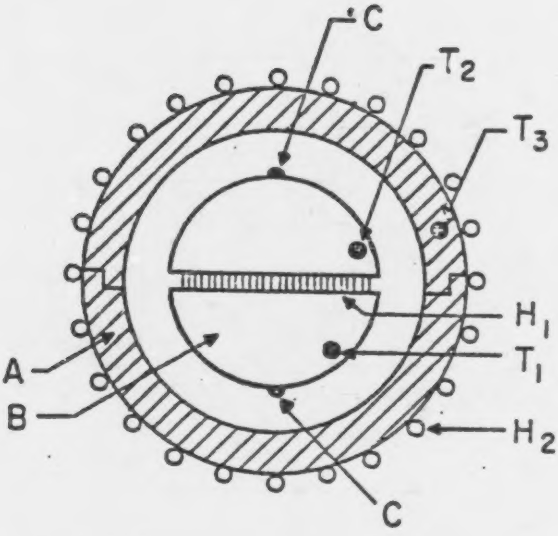

FIGURE 2. Spherical graphite calorimeter with solid core.[33] A — Shell outer diameter 2.05 cm; inner diameter 1.28 cm; graphite. B — Core: diameter 1.00 cm; graphite. T_1, T_2, T_3 — Thermocouples: constantan vs. chromel P; 0.003 in diameter wires imbedded in holes with epoxy resin. H_1 — Core heater made of electrically conducting resin. C — Copper spots: a No. 43 copper wire was attached to each spot with epoxy resin. H_2 — Shell heater: Karma resistance wire; Diameter 0.003 in; attached to shell with epoxy resin; space between wires is about 0.2 cm: (From Petree, B. and Lamperti, P., *NBS.J. Res.*, 71C, 19, 1967. With permission.)

by activating heating wires in the exchangeable part, which then can be replaced by a dosimeter or a stack of dosimeter films having the same size and shape as the calorimetric body.

B. Ferrous Sulfate Dosimetry

In radiation processing applications particularly with X- or gamma-ray sources, one of the most useful reference dosimeters is an aqueous sulfuric acid solution of ferrous sulfate ("Fricke" dosimeter).[28-30] Procedures for its use may be found in the literature for both photon and electron radiations.[3,29,31,33]

In its simplest form, it is, namely, an aerated solution containing 1 m*M* ferrous sulfate or ferrous ammonium sulfate and 1 m*M* sodium chloride in aqueous solution containing 0.8 *N* sulfuric acid. This dosimeter may be used accurately to measure absorbed doses from 3 to 40 krad (30 to 400 Gy). The Fe^{2+} ions in aqueous solution are oxidized by irradiation and form Fe^{3+} ions, which have an absorption peak in the ultraviolet at ~305 nm. By measuring the *change in absorbance* (optical transmission density) (ΔA) at this wavelength and knowing the *molar absorptivity* (molar extinction coefficient) (ε) of Fe^{3+} ions at 305 nm ($\varepsilon = 2195\ l \cdot mol^{-1} \cdot cm^{-1}$ at 25°C), as well as the radiation yield (G-value) of ferric ions ($G_{Fe^{3+}} = 15.6$ ions per 100 eV $= 9.74 \times 10^{17}$ ions per joule for ^{60}Co gamma rays), the absorbed dose (D) in rads (or grays) in the solution may be determined within nominal precision limits of about ±1%:

$$D = \frac{\Delta A \cdot N}{\rho \cdot G \cdot \varepsilon \cdot d} \cdot \frac{b}{k}$$

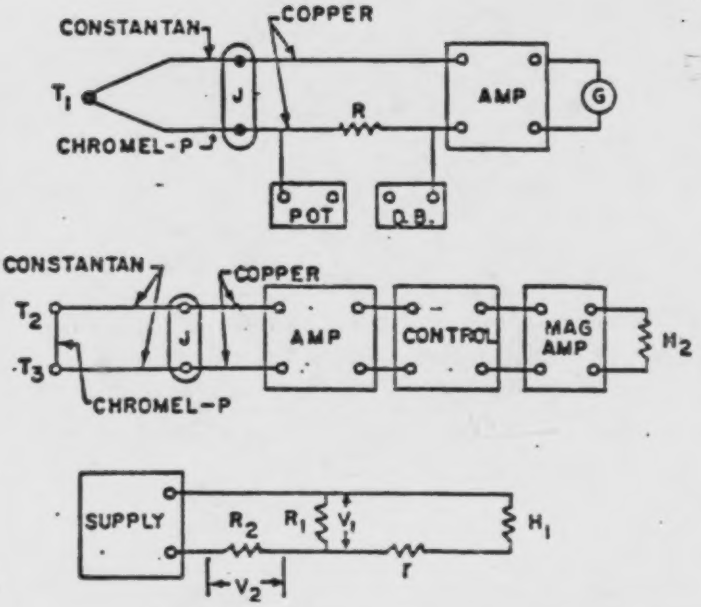

FIGURE 3. Electrical circuits used with calorimeters.[13] (See Figure 2) Top — Core temperature measurement; T_1, core thermocouple; J, constant temperature reference cell; R, 10 ω manganin standard; POT, 0—1.6 N potentiometer; D.B., 5 dial decade resistor, 0 to 111, 110ω; AMP, contact modulated d-c amplifier; G, microammeter with zero at center of scale. Middle — Shell temperature control: T_1, core thermocouple; T_3, shell thermocouple; J, constant temperature reference cell; AMP, contact modulated d-c amplifier; CONTROL, 3 mode current: adjusting controller; MAG AMP, magnetic amplifier; H_2, shell heater winding. Bottom — Electrical calibration: SUPPLY, constant current generator; R_1, R_2, wirewound resistors; r, copper lead wires; H_1, core heater. (From Petree, B. and Lamperti, P., *NBS J. Res.*, 71C, 19, 1967. With permission.)

where N = 6.022×10^{23} mol^{-1} (Avogadro's number), ϱ = 1.024 g/cm^3 = 1.024×10^3 kg/m^3 (density of solution), d = the optical pathlength (usually d = 1.00 cm = 0.0100 m), b = 1.602×10^{-14} rad · g · eV^{-1} (energy conversion factor), and k = 10^3 $cm^3 \cdot l^{-1}$ (volume conversion factor).

(Note that when D is expressed in units of grays and the others also in SI units, b and k are unity.) A general expression may be given as follows: at 25°C, D = (2.751×10^4) · ΔA in rads or D = (2.751×10^2) · ΔA in grays, for an optical pathlength of 1.0 cm. The main requirements are cleanliness and purity of ingredients, including the use of water triply distilled for the practical elimination of organic impurities. Demineralized water or simply distilled water is not acceptable. The G-value decreases as absorbed dose rates exceed $\sim 10^6$ rad · s^{1} ($\sim 10^4$ Gy · s^{-1}).[33]

The response of the ferrous sulfate dosimeter does not vary appreciably with temperature during irradiation, but there is a variation of optical density reading with temperature during spectrophotometry. During analysis in the temperature range of 15° to 35°C, the value of the molar absorptivity, ε, varies with temperature as follows:

$$\varepsilon_{Fe^{3+}}(\text{at } 25°\text{C}) = \frac{\varepsilon_{Fe^{3+}}(\text{at } t°\text{C})}{1 + k(t - 25)}$$

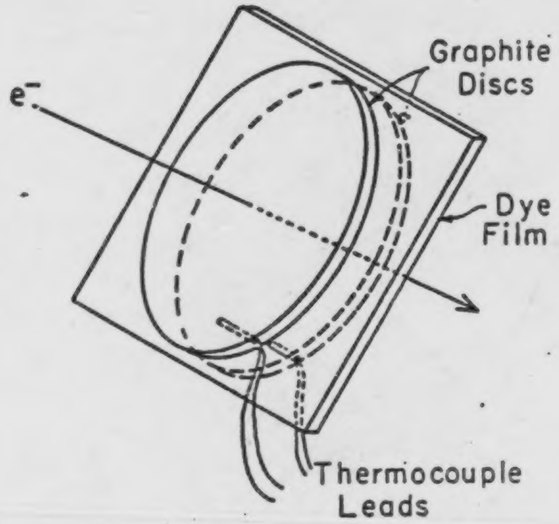

FIGURE 4. 1.0-mm thick graphite calorimeter discs for calibrating the response of thin dye film dosimeter placed between the discs.[33] (From International Atomic Energy Agency Publ. No. SM123/43, 581. With permission.)

where $\xi = 0.007\ (^\circ C)^{-1}$ (the temperature coefficient of ε).

The upper range of response of this reference dosimeter may be extended to 200 krad (2 kGy) by using a higher concentration of ferrous sulfate or ferrous ammonium sulfate (10 m*M*) and saturating the solutions with oxygen gas. This system is sometimes called the "super Fricke" dosimeter.[29] This solution has a higher radiation yield of ferric ions ($G_{Fe^{3+}}$ = 16.1 per 100 eV = 1.005×10^{18} ions per J for ^{60}Co γ-rays), but when used at very high absorbed dose rates in electron beams (i.e., $\dot{D}$ up to 10^{10} rad · sec^{-1}; 10^8 Gy · sec^{-1}), NaCl must not be used to scavenge impurities, because it may cause variation of G-value with dose rate.

Another analytical method, namely electropotentiometry, is also useful with ferrous sulfate dosimeter solutions. Either the electrolytic ferric ion charge is measured with a platinum electrode[34] or NaF is added to the solution and complexing of Fe^{3+} and F^- ions causes a variation in the potential across a fluoride selective ion electrode membrane, as measured potentiometrically against a reference electrode of a pH meter.[35] The useful range and Fe^{3+} ion yield (G-value) are the same as for the ferrous sulfate dosimeter (at pH 2.7) analyzed spectrophotometrically.

C. Ferrous-Cupric Sulfate Dosimetry

A reference system for higher doses that is a variation on the ferrous sulfate solution is the ferrous-cupric dosimeter.[28,36-40] It consists of 1 m*M* ferrous sulfate or ferrous ammonium sulfate and 10 m*M* cupric sulfate dissolved in aqueous solution containing 0.1 *N* sulfuric acid. The ferrous ion under irradiation is oxidized to ferric ion approximately linearly with doses up to $\sim 5 \times 10^5$ rads (5 kGy).[40] With this solution doses as low as 10^5 rads (1 kGy) may be read within nominal precision limits of about ±2%. Doses as large as several megarads may be determined if the concentrations of the ferrous and cupric salts are increased by a factor of six and the dosimeter is diluted suitably after irradiation.

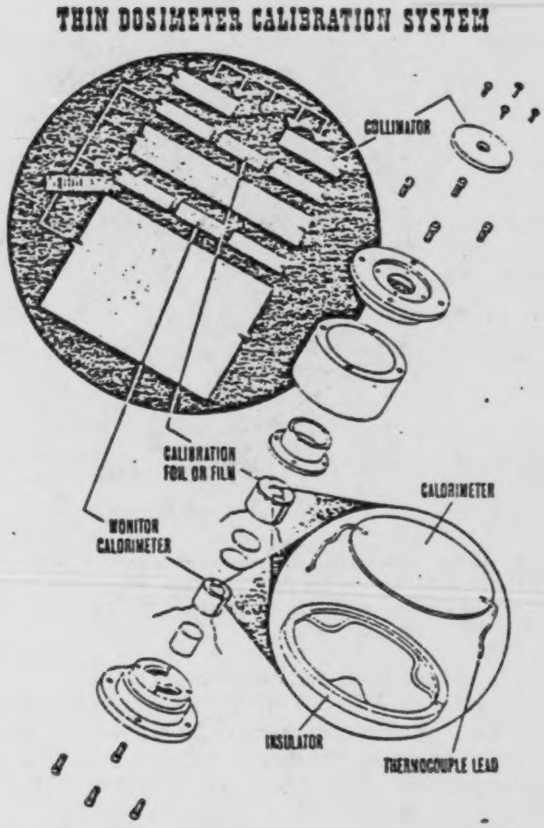

FIGURE 5. Calorimeter "sandwich" and collimator for calibrating the response of thin-film dosimeters at different depths in various media, for both continuous and pulsed electron beams. The calorimetric body may consist of a thin graphite disc or a metal foil and the medium may be plastic or metal.[16] (From Chappell, S. E. and Humphreys, J. C., *IEEE Trans. Nucl. Sci.*, 19, 175, 1972. With permission.)

The wavelength for spectrophotometric analysis is 302.5 nm, with the same molar sorptivity ($\varepsilon_{Fe^{3+}}$ = 2195 $\ell \cdot mol^{-1} \cdot cm^{-1}$) as the ferrous sulfate solution. The ab- rbed dose is determined as with the Fricke dosimeter, except that the yield is much aller ($G_{Fe^{3+}}$ = 0.63 × 10^{-3} per 100 eV = 3.93 × 10^{16} J^{-1} for air-free solution and $_{Fe^{3+}}$ = 0.76 per 100 eV = 4.74 × 10^{16} J^{-1} for O_2-saturated solution, and the density the solution is slightly smaller (ϱ = 1.001 $g \cdot cm^{-3}$).

A problem with this system is its instability after it is made up and before it is adiated. Actually the effect is due to back reaction during irradiation, the extent of ich depends on whether or not a small amount of Fe^{3+} is already present.[48] Some ers make up fresh solutions daily, rather than correct for this discrepancy. By preir- diation of the dosimeter to a dose of ~10^5 rads (1 kGy) or by adding a small concen- tion of ferric ion before storage prior to irradiation, the apparent instability is di-

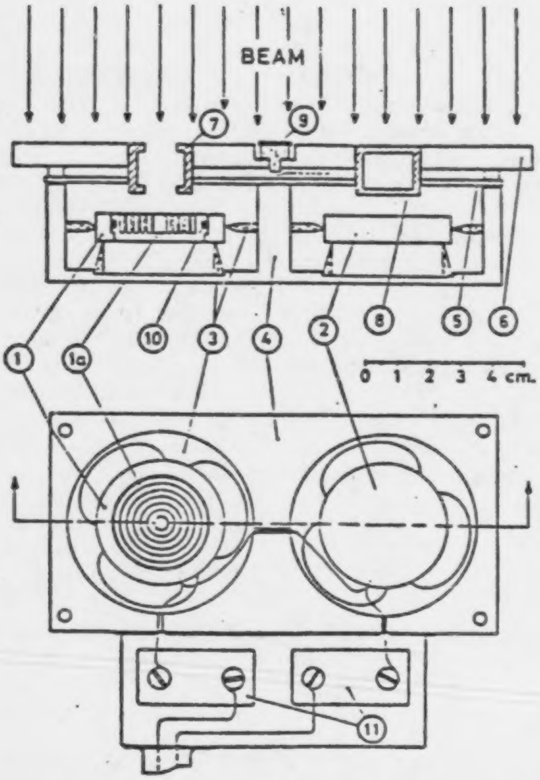

FIGURE 6. Calorimeter shown in elevation and plan news, with a calorimetric body (graphite, metal, etc.) that can be exchanged for thin dosimeters or stacks of dosimeter, and with a duplicate reference calorimetric body shielded from the radiation beam. Calibration is achieved by heater wires around the calorimetric bodies.[44] (1) Calorimetric body, fixed part; (1a) Calorimetric body, exchangeable part; (2) Reference body; (3) Perspex supports; (4) Aluminum matrix; (5) Aluminum; (6) Aluminum shield; (7) Brass collimator; (8) Dummy collimator; (9) Beam current monitor; (10) Calibration heater; (11) Copper connectors. (From International Atomic Energy Agency Publ. No. SM160/31, 312. With permission.)

minished somewhat at the decreasing expense of the upper limit of the linear portion of its response. In this case the absorbance of the unirradiated solution is more stable and increases by only about 2%/week. The variation of temperature during irradiation has a negligible effect on the response of the ferrous-cupric dosimeter. Spectrophotometric reading of absorbance, on the other hand, is temperature dependent, with an increase in absorbance of 0.7%/°C.

D. Ceric Sulfate Dosimetry

Another aqueous chemical dosimeter is based on the radiolytic reduction of ceric ion to cerous ion in dilute sulfuric acid solution.[28,30,41-43] In concentrations of 0.03 or 0.1 *M* ceric sulfate or ceric ammonium sulfate in an aqueous solution containing 0.8 *N* sulfuric acid, it can be used at relatively large absorbed dose levels (10^5 to 1.5×10^7 rads; 10^3 to 1.5×10^5 Gy). Variations include other concentrations of ceric ion to attain higher dose levels (up to 1.4×10^8 rads; 1.4 MGy)[44] or, in fact, addition of cerous ion before irradiation in order to manipulate the useful absorbed dose range (10^5 to 10^8 rads; 10^3 to 10^6 Gy).[45] During irradiation, the ceric ions are reduced to cerous ions and cerous ions are oxidized, the net G-value showing the difference. The concentration of cerous ions before irradiation is therefore important to the final yield of cerous ions. After irradiation and before reading on a spectrophotometer at 320 nm wavelength, the solution must be diluted as much as 50- to 100-fold with 0.8 *N* aqueous sulfuric acid.[42,44,45]

The initial concentrations are chosen on the basis of dose range; the dilution factor depends on how much the absorbance at 320 nm must be decreased in order for absorbance values to be measured readily and for the Lambert-Beer law to hold.

The value of the molar absorptivity (ϵ) of the ceric ion at 320 nm in 0.8 *N* aqueous sulfuric acid is 5610 $l^{-1} \cdot mol^{-1} cm^{-1}$ at 25°C. The yield of cerous ion when irradiated with ^{60}Co gamma radiation varies somewhat with initial concentration of ceric ion. $G_{Ce^{3+}} = 2.34$ per 100 eV $= 1.46 \times 10^{17}$ J^{-1} for an initial concentration of 0.2 m*M* (dose range 10^4 to 6×10^4 rads; 0.1 to 0.6 kGy), and $G_{Ce^{3+}} = 2.04$ per 100 eV $= 1.27 \times 10^{17}$ J^{-1} for an initial concentration of 50 m*M* (dose range 4×10^6 to 2×10^7 rads; 40 to 200 kGy).[42] There have also been reports of G-values for cerous ion production of 2.45 per 100 eV $= 1.53 \times 10^{17}$ J^{-1} (see Taimuty[41]). The absorbed dose (D) in rads is calculated as follows:

$$D = \frac{\Delta A \cdot f}{\rho \cdot G \cdot \epsilon} (9.65 \times 10^8)$$

where f is the dilution factor (final volume/initial volume), ϱ is the density of solution (nominally 1.03 $g \cdot cm^{-3}$), and ΔA is the change in optical density at 320 nm wavelength.

The following general observations may be made about the ceric sulfate dosimeter:

1. Although it is true that dosimeter solutions involving combinations of ceric and cerous ions before irradiation are not as sensitive to error due to impurities as are ceric sulfate solutions alone,[43,46] any solution containing ceric sulfate can be expected to show extreme sensitivity to organic impurities because of its intrinsic effectiveness as an oxidizing agent. Hence, excessive G-values for Ce^{3+} ion production are generally due to the presence of impurities. For this reason, it is important that water triply distilled in quartz glass be used and that only exceedingly clean glass containers be used, even when handling after irradiation.[30] With such meticulous care, precision limits of about ±1% and accuracy limits of about ±3% have been claimed.[43]
2. As with many other chemical dosimeters, the ceric sulfate system may be standardized. Standard colorimetric titration determines cerous ion concentration,[41,43] in which As_2O_3 is used as a reducing agent and OsO_4 and ferroin solution is used as an indicator.
3. The dosimeter solutions are generally reported to be relatively insensitive to oxygen concentration; nevertheless, for optimum accuracy, deaeration (N_2- or Ar-saturation) before sealing the ampules is recommended.[43,46]
4. The solutions are somewhat sensitive to light, especially after dilution, so that spectrophotometric analysis and handling must take place under subdued illumination.[45]
5. Dose-rate dependence of response in the form of increase of cerous ion yield occurs at absorbed dose rates exceeding 10^8 rad · sec^{-1}.[30,47]
6. Temperature dependence of response is variable, depending on oxygen concentration.[46] G-values have generally been found to decrease by ~0.2%/°C rise in temperature.

7. Because of fairly high concentration of cerium in the dosimeter solutions, the radiation response of the dosimeters has a different absorption cross-section from water or most biological systems, especially for ionizing photons below 100 keV.[45,46]
8. Potentiometric analysis of the ceric-cerous sulfate dosimeter solution, using platinum electrodes, permits readings of absorbed doses of between about 0.06 and 4 Mrad (0.6 to 40 kGy), depending on the ratios of concentrations of ceric and cerous ions.[49,50] A commercial reader and supply of sealed ampules is available for electropotentiometry.* Dose readings with this system are claimed to be reproducible to within about ±3%.

E. Miscellaneous Reference Dosimetry

A number of other primary chemical dosimeters have also been used for calibration of routine dosimeters, but these are generally not as accurate or convenient as the systems described above. For those interested in investigating the properties of a few other reference systems, we list some of the major ones along with their useful dose ranges and sources of information about them:

1. Ethanol-chlorobenzene (titration method): 4×10^4 to 5×10^6 rads; 0.4 to 50 kGy.[51-53]
2. Aerated aqueous oxalic acid solution: 10^6 to 10^8 rads; 10^4 to 10^6 Gy.[54,55]
3. Aerated aqueous benzene solution: 5×10^3 to 7×10^4 rads; 50 to 700 Gy.[56]
4. Aerated aqueous sodium formate solution: 10^6 to 10^8 rads; 10^4 to 10^6 Gy.[57]
5. Aerated aqueous potassium thiocyanate solution (for pulsed beam application).[58]
6. Oxygenated aqueous ferrocyanide solution (for pulsed beam application).[59]

Since these systems are not so widely used or established as are the ferrous, ferrous-cupric, or ceric sulfate dosimeter, it is especially important to check repeatability and measured values of radiation chemical yields.

IV. ROUTINE TRANSFER DOSIMETRY SYSTEMS AND PROCEDURES

This category of measurement systems for use in interlaboratory comparison studies is confined to those dosimeters or dose-rate meters having a reproducible radiation response that is sufficiently stable in order to permit intercomparisons or readings of absorbed dose or dose rate at various times after irradiation, without the need for corrections due to instability.

A. Thermoluminescence Dosimetry (TLD)

Many crystalline materials when irradiated store energy in the form of filled electron and hole traps. These filled traps are often permanent enough at room temperature to provide readings of absorbed dose by the emission of light photons due to subsequent heating. The electron or hole in its trap is thus released to recombine with its counterpart, accompanied by fluorescence radiation.[2,40,41] With proper calibration, measurement of this luminescence gives a determination of absorbed dose due to the original irradiation. Crystalline materials commonly used as TLD materials are natural forms of LiF or CaF_2 or they may be CaF_2, $CaSO_4$, or $Li_2B_4O_7$ to which have been added trace amounts of manganese or other elements (Dy, Na, Ti, etc.) as trapping centers. The material is used either as a powder, pressed pellets, sealed glass tubes or bulbs containing heaters and TLD material, or impregnated plastic wafers.

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* Atomic Energy of Canada Ltd., Commercial Products, P.O. Box 6300, Postal Station "J", Ottawa, Canada.

The heating cycle is strictly controlled in order to provide a glow peak in the thermoluminescent emission at temperatures between 110 and 260°C, depending on the material. The emission spectra generally range between wavelengths of 350 and 600 nm, such that the readout is made with a photomultiplier interfaced with the heating system. By using this amplification of the optical signal, it is possible to measure very small doses represented by the emission of extremely low levels of luminescence. Doses as small as 10^{-6} rads (10^{-8} Gy) can be measured in this way with CaF_2:Mn in a sealed glass bulb combined with a commercial reader. LiF and CaF_2:Mn can be used in the form of loose powder or impregnated plastic (e.g., Teflon® or polyethylene) wafers to measure doses up to ~10^5 rads (10^3 Gy). $Li_2B_4O_7$:Mn has been used for doses up to nearly 10^6 rads (10^4 Gy) before saturation effects occur. Certain forms of optical grade LiF show increasing thermoluminescence with dose up to greater than 10^8 rad (10^6 Gy), but the TLD reader must be capable of analyzing high-temperature glow peaks (~450°C), and supralinearity effects must be considered.[62] CaF_2:Dy can be used up to nearly 10^5 rads with no exhaustion effects due to repeated annealing after total doses up to 2 × 10^8 rads.[63]

One problem with most TLD dosimeters for biological applications is that the response to ionizing photons and electrons over a broad spectrum, particularly at energies <150 keV and >10 MeV, shows marked energy dependence, due to differences in absorption characteristics relative to most biological substances.[2,61,64]

Some of the properties of the TLD systems are given in Table 1 for applications in food irradiation.

B. Radiochromic Dye Dosimetry

Solutions of certain colorless dye precursors, usually leuco-triphenylmethane dyes, such as the cyanides, carbinols, bases, or methoxides of pararosaniline, malachite green, new fuchsin, etc. make useful dosimeters.[65-68] They can be made into gels, liquids, thin films, impregnated papers, or thermoset polymers that form permanent colors upon irradiation, with increase of optical density (or absorbance) that is approximately linear with absorbed dose over a wide dose range; the usual method of analysis is spectrophotometry.[65,68-73]

These dosimeters may be put into two general categories: (1) liquid systems with a useful dose range of about 10^3 to 10^6 rads (10 to 10^4 Gy),[67,70,71] and (2) solid systems with a useful range of about 10^3 to 10^8 rads (10 to 10^6 Gy).[68,72,74]

1. Liquid Radiochromic Systems

These are available commercially in sealed glass ampules*, or they may be made using stock chemicals. They have a specific G-value for dye yield and they have a specific molar absorptivity for a given radiolytic product dye at the wavelength of maximum absorption in the visible spectrum. The dye precursor itself can be synthesized from the parent dye, but because of variations in the purity of industrial supplies of dyes, the response of each new batch of dye system must be calibrated against the response of a reference dosimeter.[70,75]

A typical radiochromic liquid dosimeter solution consists of the following:[70] pararosaniline cyanide dissolved at a concentration of 5 m*M* in fresh reagent grade 2-methoxy ethanol, to which is added a carboxylic acid (e.g., glacial acetic acid or propionic acid) to make a concentration of 17 m*M*. It may be used and stored either in glass or in certain plastics (polyethylene, polystyrene, polypropylene, etc.) and does not require high purity and extreme cleanliness as do most aqueous chemical dosimeter systems. Aerated solutions provide readings of absorbed dose in the range 10^4 to 10^5 rads (10 to 10^3 Gy). In order to achieve dose measurements up to 10^6 rads (10^4 Gy) without saturation effects, it is necessary to add oxygen gas or a weak oxidizing agent (e.g., 30 m*M* nitrobenzene), in which case the G-value is different from that of aerated solutions. The yields in terms of dye molecules formed per 100 eV of radiation energy absorbed are as follows for 5 m*M* solutions of pararosaniline cyanide in 2-methoxy ethanol described above: G-value (aerated) = 0.31[76]; G-value (oxygenated) = 0.12.[76] The molar absorptivity at the wavelength of the maximum of the dye absorption band (549 nm) is $1.4 \times 10^5 l \cdot mol^{-1} \cdot cm^{-1}$.

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* Far West Technology, Inc., 330 S. Kellogg, Goleta, Calif., 93017.

One important precaution in using these radiochromic dye solutions is to protect them from the effects of light, since optical wavelengths below about 340 nm cause photolytic dye formation. Such can be accomplished by storage in amber glass, by using only yellow or indirect illumination during handling or by placing a clear UV absorbing plastic film over windows and light fixtures. Important advantages of these systems are their stability before and after irradiation[76,77] and the absence of dose-rate dependence of response, even for dose rates up to 10^{14} rad $\cdot$ s^{-1}.[78] There is no effect of temperature during spectrophotometry, but the G-value increases by approximately 0.7%/°C rise in temperature during irradiation.[77] Nominal reproducibility of dose readings is specified to be about ±3%.[3]

Table 1 lists the important properties of these dosimeter systems.

2. *Solid Radiochromic Systems*

This group is commercially available* and consists mainly of solid gels or thermoset polymers from 1 to 10 mm thickness (dose range ~10^3 to 5×10^5 rads; 10 to 5×10^3 Gy), impregnated papers or plastic (10^5 to 10^7 rads; 10^3 to 10^5 Gy) or thin plastic films or coated films (10^5 to 10^7 rads; 10^3 to 10^5 Gy).[73] Films may also be made either by thermosetting a monomer solution of the dye precursor[79] or by casting from polymer solution of the dye.[73] The response of the thin films consisting of UV-transparent plastic substrate material can be amplified by irradiating in combination with a radiographic screen (LaOBr:Tm) that emits ultraviolet radiation of ~300 nm wavelength.[80] In this case, doses as low as 10 krad may be measured with precision adequate for some applications (approximately ±5%).

These dosimeters are colorless until irradiated, whereupon they take on a permanent color, as illustrated in Figure 7. They show a prominent absorption band in the visible spectrum, with an absorbance increase that is approximately linear with dose up to about 2 Mrads (20 kGy), as shown in Figures 8 and 9. Since the color is stable and the response does not change with absorbed dose rate up to ~10^{14} rad/sec(10^{12} Gy/sec)** and is only moderately affected by temperature variation during irradiation, these dosimeters are convenient for determining doses under a wide variety of irradiation conditions. The radiochromic dosimeters may be used in several applications as follows:

1. Calibrate the response function (absorbance change vs. absorbed dose) with a standard gamma-ray source and evaluate production doses due to either continuous, pulsed, scanned X-ray, or electron beams.[81]
2. Perform interlaboratory comparisons of dose interpretations by mail.[81]
3. Carry out dosimetry over a wide range of temperatures (−78° to + 100°C).[81]
4. In different food products, determine values and positions of D_{min}, D_{max}, and U = D_{max}/D_{min} for a given process, as a means of achieving quality control in radiation processing.[4,81]

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* Far West Technology, Inc., 330 S. Kellogg, Goleta, Calif., 93017.

** At very high dose rates ($\dot{D} > 10^8$ rad/sec or $< 10^6$ Gy/sec), the response with 360 nm wavelength analysis does show rate dependence.

ABSORBED DOSE, MRAD 0 0.1 0.3 1.0 1.5 2.5 4.0 10.0

FIGURE 7. Increase in absorbance (optical transmission density) with increase in absorbed dose, for a typical radiochromic thin-film dosimeter. The color may be red, green, or blue, depending on the radiochromic dye used.

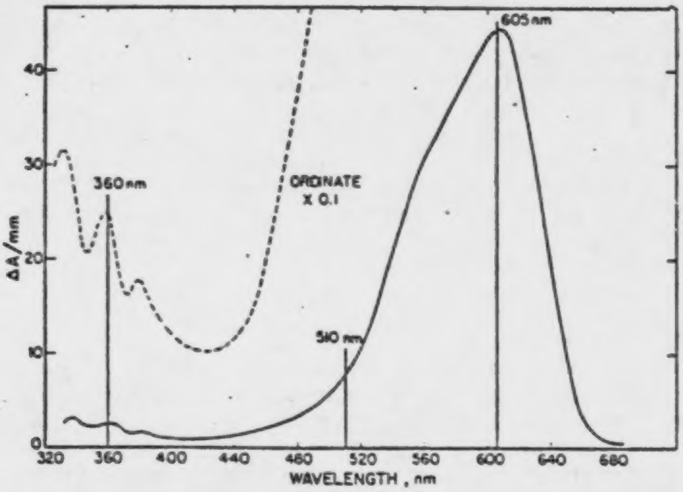

FIGURE 8. Difference spectrum for typical radiochromic dye film dosimeter in terms of the increase in optical absorbance per unit thickness (ΔA/mm) as function of wavelength of analyzing light. Typical wavelengths for analysis are given by the vertical lines. The change in absorbance (ΔA/mm) is the absorbance after irradiation minus the absorbance before irradiation, for a radiation dose of 3.0 Mrad (30 kGy).[81] (From International Atomic Energy Agency Publication No. SM222/9. With permission.)

5. Determine three-dimensional dose distributions throughout an irradiated product box.[15,83,84]
6. Use specific plastic- or tissue-equivalent dosimeter materials to measure dose in a given material of interest.[71,85]
7. Use thin-film detectors as "cavities" or small "probes" to determine absorbed dose in various irradiated media at interfaces and in complicated geometries.[15,35,69,86-89]
8. Determine transit (or "transient") doses and set irradiation parameters (conveyor speed or cycle time; source overlap, beam current, mean bulk density, etc.) to achieve proper dwell times for a given product.[3-6]
9. Determine statistical dose variations due to planned or unplanned product variability, bulk density change, or conveyor breakdown.[83]
10. Make visual indication of irradiation for inventory control ("go — no go" monitoring).[4]

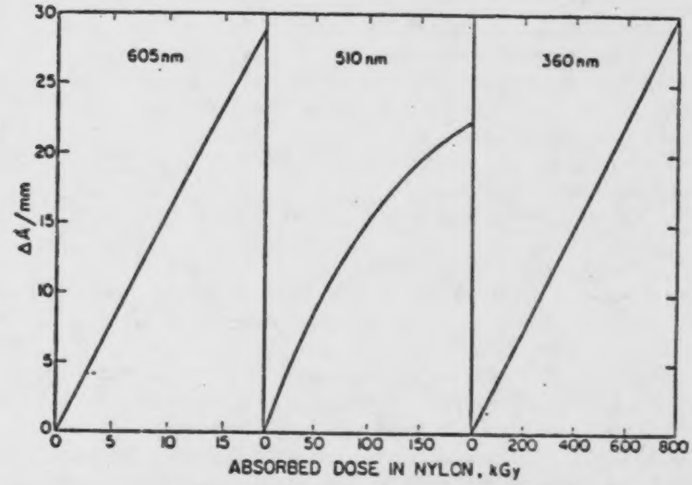

FIGURE 9. Calibration curves for typical radiochromic dye film dosimeter, in terms of the increase in optical absorbance per unit thickness (ΔA/mm) as a function of absorbed dose in the dose meter material (Nylon), for wavelengths of analysis indicated in Figure 8.[81] (From International Atomic Energy Agency Publ. No. SM222/9. With permission.)

Despite the relatively high degree of reproducibility and accuracy of dose measurement afforded by these radiochromic dye systems, certain precautions are necessary for minimizing imprecision and error:[73,84]

1. Corrections are needed for variations of response with large temperature variations during irradiation.
2. The dosimeters must be protected from bright ultraviolet illumination which can be achieved by placing clear chemically-treated polyethylene terephthalate film* over windows or fluorescent light fixtures.
3. With Nylon-base radiochromic dye films or others with water permeability, there must be protection from excessive moisture during irradiation.
4. Each new batch of the commercially supplied dosimeter should be calibrated or cross-checked.

Table I lists characteristics of these systems for food irradiation applications.

C. Ceric-Cerous Sulfate Dosimetry (Potentiometric Analysis)

Mathews[49] has developed a method of dosimetry using acidic aqueous solutions of ceric and cerous sulfate (see Section III.D), but rather than analyzing the quantity of radiolytically reduced cerium by titration or spectrophotometry, it is accomplished by electrochemical potentiometry.[49] The apparatus consists of an electrochemical cell and a precision voltmeter for reading differences in redox potential between platinum electrodes separated by a sintered glass ceramic plug between irradiated and unirradiated solution. The apparatus, as well as calibrated prepared dosimeter solutions in sealed 2-m*l* glass ampules, are commercially available.** It is claimed that, depending on the initial ceric ion concentration, absorbed doses from either 0.06 to 0.5 Mrad (0.6 to 5 kGy) or 0.5 to 4 Mrad (5 to 40 kGy) can be read with nominal precision limits of about ±2%, over an ambient temperature range of 0 to 50°C. The problem of impurities causing error and poor reproducibility is less with this system than with the reference ceric sulfate dosimeter that is analyzed spectrophotometrically (see Section III.D). The dosimeter solution, it is said, can be irradiated while held in plastic vials rather than sealed glass, without loss of accuracy.

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* "Weatherable" Mylar® from Du Pont de Nemours Corp., Wilmington, Del., 19801 or uvx Llumar® from Martin Processing, Martinsville, Va., 24112.

** Atomic Energy of Canada Ltd., Commercial Products, P.O. Box 6300, Postal Station "J", Ottawa, Canada K2A 3W3.

Properties of this method of dosimetry are shown in Table 1.

D. Ethanol Chlorobenzene Dosimetry (Oscillometric Analysis)

A routine method of dosimetry has been developed for ethanol-chlorobenzene solutions (see Section III.E), with dose interpretations being made by means of radio-frequency oscillometry of unopened glass ampules containing the solutions,[90,91] rather than by titration of solutions from ampules opened after irradiation.[92] The commercially available apparatus* contains an oscillator with a frequency of 140 MHz, the dosimeter ampule being placed between the capacitor plates of a parallel oscillator circuit. There is no galvanic contact with the dosimeter and the ampules do not have to be opened for dose interpretation. Differences in the relative impedences of the irradiated solutions due to differences in absorbed dose are read on a scale and provide a typical calibration curve as shown in Figure 10. In order to cover different parts of the absorbed dose range, different calibration curves can be obtained by changing the sensitivity setting of the instrument and reading dosimeter ampules irradiated at different doses over that range. The nominal dose limits by this method are 0.1 to 40 Mrad (1 to 400 kGy) at a yield of $G = 5.0$ Cl$^-$ ions per 100 eV, but by changing the chlorobenzene concentration, the upper limit of readings at ±3% precision is ∼100 Mrad (1000 kGy). The dosimeter solutions in sealed ampules are relatively stable before and after irradiation. They may also be held in polyethylene vials without error as long as dimensions and contents of the vials are identical.

Table 1 shows characteristics of this dosimeter.

V. ROUTINE DOSIMETRY FOR INTRALABORATORY USE

Other successful methods of dosimetry for use within a given laboratory or simultaneously in separate laboratories include those that give reproducible and accurate dose readings, as long as (1) the response is properly calibrated in terms of radiation effect-vs.-dose and (2) sources of systematic error are accounted for (instability, environmental factors, batch differences, etc.). This category may include many dosimeters, a number of which are described briefly here. A general precaution with these systems is to limit their use to conditions similar to those under which they have been calibrated."[73]

A. Colorless Polymethylmethacrylate

Undyed polymethylmethacrylate (PMMA) thin plastic (1 to 3 mm) (having commercial trade names such as Lucite®, Perspex®, Plexiglas®, etc.) has been used with success to measure absorbed doses from approximately 10^5 to 10^8 rads.[93-95] The radiation effect of interest is the formation of a broad absorption band in the ultraviolet. In a "clear Perspex®" made especially for dosimetry**, readings of absorbance change are most successfully carried out at 314 nm, at which wavelength variations in

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* Medimpex, P.O. Box 126, H-1308 Budapest 5, Hungary.

** "HX Perspex®", which is supplied by the U.K. Panel on Gamma Ray and Electron Beam Irradiation, National Physical Laboratory, Teddington, Middlesex, U.K.

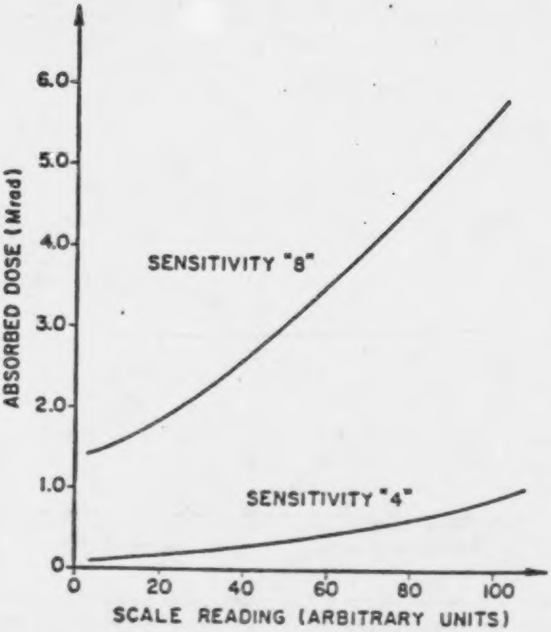

FIGURE 10. Oscillometric calibration curve for ethanol chlorobenzene dosimeter: conductivity scale reading (arbitrary units) as a function of absorbed dose, with armature sensitivity settings to accommodate two dose ranges of interest.[98] (From International Atomic Energy Agency Publ. No. SM160/15, 375. With permission.)

dose reading due to instability are minimal during the first 24 hr of storage after irradiation.[96] Recommended detailed procedures for using this dosimeter are given in the literature.[3]

In using this system for making routine radiation measurements in research, commissioning, or on a production line, the following precautions are necessary to minimize error and to achieve nominal precision limits (approx. ±3%):

1. Clean the material carefully with ethyl alcohol before use.
2. Read the absorbance before irradiation and within a few hours after irradiation.
3. Protect the system from bright light.
4. Avoid touching or scratching faces of the plastic.
5. Avoid temperatures above 45°C during or after irradiation.
6. Avoid dose rates exceeding 10^8 rad/s (10^6 Gy/s).
7. For use at doses less than 0.3 Mrad (3 kGy), treat in a vacuum oven before irradiation (<1.35 Pa at 130°C) for several minutes to drive out oxygen (time determined by dosimeter thickness) and seal in packets.
8. Monitor the thickness carefully.
9. Calibrate each dosimeter batch.

Some of the characteristics of these systems are given in Table 1.

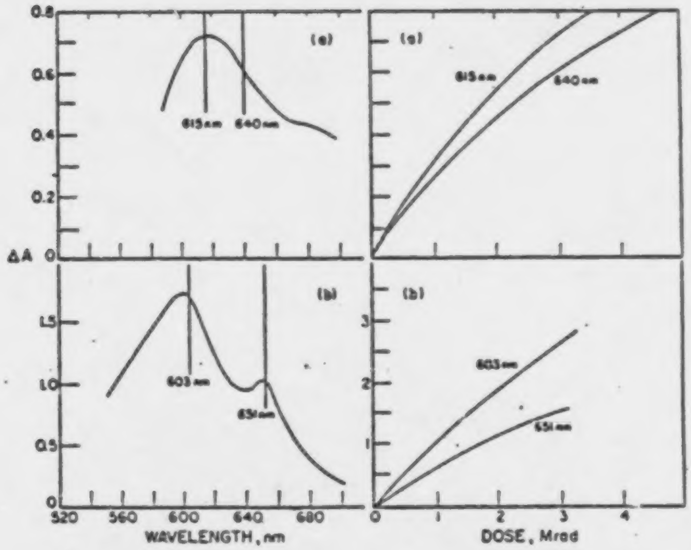

FIGURE 11. On the left, change in absorption spectra of dyed Perspex® dosimeters due to irradiation with ^{60}Co gamma rays to an absorbed dose of (a) 3 Mrad; (b) 2 Mrad. On the right, calibration curves of change optical density (ΔA) at the indicated wavelengths as a function of dose (D): (a) Red Perspex® type 4034; (b) Amber Perspex® type 3042.[98] (From Gaughran, E. R. L. and Goudie, A. J., *Sterilization by Ionization Radiation*, Multiscience, Montreal, 1974, 239. With permission.)

B. Dyed Polymethylmethacrylate Dosimetry*

PMMA that contains certain dyes can be used to determine absorbed doses of approximately 0.15 to 2 Mrad (1.5 to 20 kGy) in the case of Amber Perspex® 3042 and approximately 0.5 to 5 Mrad (5 to 50 kGy) in the case of Red Perspex® 4034.[75,97-99] Corrections must be made for instability of the radiation-induced optical absorption band at wavelengths greater than 600 nm, which is the part of the visible spectrum used for analysis in dosimetry. In most applications, the wavelengths of analysis are 603 and 651 nm for Amber Perspex® 3042 and 640 nm for Red Perspex® 4034. Thicknesses are approximately 1, 3, or 10 mm, depending on the type of dosimeter supply. The response is calibrated in terms of change of optical density (absorbance) per unit thickness (ΔA/t) as a function of absorbed dose (D). By taking into account instability factors, environmental effects, nominal precision limits within a batch have been specified to be approximately ±2% or 3%. Typical spectral absorption bands in terms of difference in optical absorbance before and after irradiation are shown on the left in Figure 11. Shown on the right side for a given batch of dosimeters are calibration curves, consisting of change in absorbance per unit thickness (ΔA/mm) at indicated wavelengths as a function of absorbed dose (D). By using these characteristic curves, dose interpretations are possible and provide useful values of D_{min}, D_{max}, and $U = D_{max}/D_{min}$ after strategic placement of dosimeter in product boxes for irradiation[83,99] (see Section V.B.2).

Detailed procedures for using these dosimeters are given in the literature.[3] Dosimeter characteristics for red and amber Perspex® are shown in Table 1.

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* Red Perspex®, type 4034, or Amber Perspex®, type 3042, as supplied individually in sealed packets by A.E.R.E., Harwell, Didcot, U.K.

C. Polyvinylchloride Dosimetry (PVC)

Polyvinylchloride films (∿1 mm thick) have been used successfully in practical applications of food irradiation and sterilization of medical supplies, particularly for imaging electron beam dose patterns, where relatively large quantities (long strips) of this relatively inexpensive plastic are used to monitor lateral dose distribution in product boxes that pass under an electron beam scanner.[28,100-103]

The interpretation of dose level (approximate range 0.5 to 6 Mrad; 5 to 60 kGy) is achieved by spectrophotometry of an absorption band at 395 nm, which is developed after irradiation by means of heat treatment (e.g., 50°C for about 1 hr, 60°C for about 15 min, or 80°C for about 10 min). The response is apt to vary markedly from one film supply to another.[82,104] The thickness must be determined and absorbance values corrected accordingly. Sources of error include variations of temperature, atmosphere, and dose rate during irradiation.[75]

PVC impregnated with indicator dyes may also be used for dosimetry (see also Section V.L.12). In this case the formation of HCl by irradiation causes a change in the color of this halogenated plastic or similar plastics as well.[105] Polyvinylidene chloride (saran) has also been used for measuring doses from about 0.1 to 10 Mrad (1 to 100 kGy).[106]

Table 1 gives characteristics of this system.

D. Polyvinylfluoride Dosimetry

Having a more reproducible and linear response to radiation than PVC is polyvinylfluoride.[107] Several absorption bands in the near ultraviolet (303, 315, 352, and 386 nm) may be used for spectrophotometric determination of absorbance change as a function of absorbed dose (approximate dose range 1 to 10 Mrad; 10 to 100 kGy). The radiation-induced absorption bands are unstable for several hours after irradiation, which could cause errors in dose interpretation for long-term irradiation at different dose rates or for fractionated total doses. The thickness of each film must be monitored and the response characteristics of films of each batch must be calibrated. The response varies greatly with temperature change and with the presence or absence of oxygen (or air) during irradiation.

E. Optical Absorption of Glasses and Crystals

A number of commercial glasses and certain crystalline materials develop color centers under irradiation. Although this induced coloration is generally unstable, the measurement of absorbed doses from about 10^4 to 10^8 rads (10^2 to 10^6 Gy) is possible by using densitometry or spectrophotometry for analysis.[2,67,83,108-113]

A source of error in glass and solid-state dosimetry is the difference in radiation absorption characteristics (spectral energy dependence) of these relatively high atomic-number systems as compared with most foodstuffs. This disparity results in errors as great as 40 or 50% with degraded gamma-ray spectra and even greater for lower energy X-rays. An advantage of glass dosimeters is the greater batch-to-batch reproducibility than that of plastic films and many crystalline systems.

Relatively stable for room-temperature storage are certain color centers (F-, M-, R-, and other defect centers) that are produced by irradiation of either pure lithium fluoride or lithium fluoride with manganese impurity*[114,115] or calcium fluoride with manganese impurity.*[116] Advantages of these solid-state wafers for dosimetry are (1) a useful index of dose can be obtained by knowledge of absolute concentration of color centers represented by a given value of absorbance at a certain optical wavelength

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* Cleaved thin crystals of pure LiF, especially designed for measuring large absorbed doses by spectrophotometric analysis are available from Harshaw Chemical Company, Solon, Ohio, 44139.

(similar to molar absorptivity), which can be related to the radiation yield of color centers (i.e., G-values); (2) the dosimeter crystals can be used over and over again, as long as the color centers are properly annealed by a 1-hr 550°C heat treatment after irradiation; (3) a broad range of doses (10^4 to 10^{10} rads; 10^2 to 10^8 Gy) may be measured within approximately ±5 precision limits by choosing an appropriate assortment of analyzing optical wavelengths and intermediate temperature heat treatments (e.g., 210°C for ∿1 hr to increase response at certain analyzing wavelengths). A disadvantage is that after irradiation a 24-hr seasoning at room temperature is necessary before instability of absorption centers becomes stabilized.

F. Photoluminescence of Glasses and Crystals

Irradiation of certain glasses and crystalline solids containing a small concentration of impurities results in the production of filled traps, which upon ultraviolet illumination release holes and electrons with the emission of longer wavelength light. The intensity of this photostimulated luminescence is a measure of the concentration of ionizing radiation-induced centers, which in turn is proportional to the absorbed dose.[2,41,109,110,112,117-121] Absorbed doses from about 1 to 1.5×10^4 rad (10^{-2} to 1.5×10^2 Gy) may be interpreted in this way. The main source of error is energy dependence of response due to the presence of relatively high atomic-number ingredients.[41] On the other hand, certain plastics are also known to luminesce by photostimulation after irradiation.[122] Errors due to energy dependence are rather small with most plastics systems because polymers and organic crystalline materials as a rule have radiation absorption characteristics similar to biological tissues of interest. Since the photoluminescence signal generally increases with time of storage for one or more days after irradiation and then begins to decrease, it is recommended that readout take place within 4 hr to several days after irradiation.

It is also important that the materials be kept clean and free of surface flaws. Preirradiation optically-stimulated emission should be measured, so that the change of photoluminescence of individual dosimeters can be determined with greater reproducibility. Although change of relative humidity during irradiation has no appreciable effect, there is a marked difference of response with change in dose rate ($>10^5$ rad/s; $>10^3$ Gy/s) and with change of temperature during irradiation.

G. Lyoluminescence of Saccharides, Amino Acids, Polymers, and Salts

A form of chemiluminescence, called lyoluminescence, provides a promising method of dosimetry over a relatively wide absorbed dose range, depending on the material used (∿3×10^3 to 5×10^6 rad; 3 to 5×10^4 Gy).[123-129] The phenomenon is light emission when irradiated solids are dissolved in certain liquids. The dosimeter consists of encapsulated powder, a pressed tablet, polymer film, or pellet, having a mass of at least several milligrams. Light emission occurring during dissolution in a stirred solvent is measured over approximately 40 sec, by means of an ultraviolet-sensitive photomultiplier connected to a dc amplifier, which in turn feeds voltage signals to a frequency converter. The readout may then be made on a scaler or fast recorder in terms of an arbitrary scale reading of light yield per unit mass of solute. This reading is nearly linear with absorbed dose up to a given saturation region. The response curve must be calibrated for each material used and depends on the following factors: average particle size of the powder, the presence of gases, temperature history, the effect of ultraviolet illumination, and the concentration of free radicals. It is also sensitive to changes of pH and temperature of the solvent and shows some instability during storage. Besides being nontoxic, this dosimeter has the advantages of food-product equivalence and low cost.

Table 1 gives other characteristics of the dosimeter.

H. Electron Spin Resonance (ESR) of Bone, Amino Acids, and Polymers

ESR spectroscopic determination of free-radical concentration in certain solids can be used for dosimetry over a relatively wide dose range. Typical materials that may be used are bone,[130,131] amino acids,[132-135] or polymers such as tetrafluoroethylene.[136,137]

The radiation-induced free-radical population of these solids at room temperature is fairly stable, such that after normal room-temperature storage of the irradiated dosimeter for several days, nearly the same ESR signal amplitude occurs as that immediately following irradiation. Absorbed doses from about 10^4 to 10^9 rads (10^2 to 10^7 Gy) can be measured, depending on the substance used. One of the most useful systems is D-alanine (CH_3CHNH_2COOH), because of its similarity to certain food products. It may be used in small crystalline pellets with paraffin as binder. The dose interpretation is made within approximately ±2% precision limits by calibrating changes in the amplitudes of the ESR signal peaks, which are linear with dose up to relatively high values. A disadvantage of this system is the large cost of analytical ESR spectroscopy equipment.

Properties of this dosimeter are given in Table 1.

I. Biological Tests

Colonies of known populations of certain bacteria or other microbiological specimens may be packaged as test pieces and supplied to radiation users. They provide indication that a given biocidal effect may be achieved in terms of survival fractions after irradiation.[138-141] This method finds its main application in a radiation sterilization production facility. Usually it is limited by the greater time required for analysis and the greater limits of precision. Other methods of biological determination of effective dose after irradiation are found in several analytical methods. Examples are ESR spectrometry of seeds;[142] spectrophotometry of extracted chlorophyll solutions,[143] turbidity measurements of changes in sedimentation of grain or starch in aqueous suspensions,[144] and the analysis of phosphate released from irradiated yeast.[145]

J. Viscometry of Polyisobutylene

Radiation degradation of polyisobutylene of various molecular weights in organic solvents (e.g., heptane) causes a reduction in the viscosity of the solutions. Absorbed doses from 10^4 to 10^7 rads (10^2 to 10^5 Gy) can be determined, the useful range depending on the original molecular weight of the solute.[146-148] A capillary viscometer may be used according to ASTM Standard Method of Test for kinematic viscometry.[149] The ratio of differences is plotted on log-log paper as a function of absorbed dose. The response of each batch of the polymer must be calibrated. The degradation of other polymers as measured by viscometry can also be used for dosimetry (see Section V.L.12).

K. Dose-Rate Monitoring with Semiconductors

Silicon solar-cell diodes* can be used with a galvanometer or microammeter to monitor variations in X- or gamma-ray absorbed dose rate.[150-153] They are relatively resistant to radiation damage and are useful for gross mapping of gamma-ray fields.[154] The response is linear with change in absorbed dose rate from 5×10^2 to 10^7 rad/hr (5 to 10^5 Gy/hr). The sensor must be shielded from light and moisture. The ionization current varies with temperature, the temperature effect depending on dose rate. Even with proper calibration, this system cannot be used to measure absorbed dose rates accurately over a broad photon energy spectrum, because of energy dependence of response. Before use as a dose-rate monitor, the solar cell device must be conditioned or "aged" by irradiation to over 10 or 20 Mrad (100 or 200 kGy).

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* Hermetically sealed silicon dose rate monitors in spherical aluminum shells with various connectors are commercially available from Medimpex, P.O. Box 126, H-1808 Budapest 5, Hungary.

L. Other Miscellaneous Dosimetry Methods

An assortment of other radiation detectors can be used for intralaboratory measurement of absorbed doses in the range 10^3 to 10^8 rad (10 to 10^6 Gy). The responses must be calibrated carefully in order to achieve reasonable accuracy and precision. Some of these systems are listed below:

Reduction of activation metal chelates — The irradiation of aqueous solutions of Co^{3+} chelated in ethylene diamine-tetraacetic acid (EDTA) results in reduction to Co^{2+}, whereby absorption bands at 378 and 525 nm are bleached, giving a useful response range of ~10^4 to 10^8 rads (10^2 to 10^6 Gy).[156] This dosimeter is included in Table 1.

Optical rotation of polarization planes of sugars and other hydrocarbons — Aqueous solutions of sugars such as D-glucose, maltose, dextrose, etc., show changes of optical activity due to large doses of ionizing radiation (1 to 5 × 10^8 rad; 1 to 5 × 10^6 Gy.[157-161] Although the response of this inexpensive dosimeter needs calibration, it is relatively independent of batch and temperature during irradiation and is similar to many foods in radiation absorption characteristics (see Table 1).

Print-out of photographic emulsions — Radiographic silver-halide emulsions or dosimeter films when irradiated to large doses (10^3 to 10^7 rads; 10 to 10^5 Gy) undergo darkening without chemical development, due to print-out image formation, i.e., nucleation of stable visible silver deposits.[162,163] Densitometry with certain narrow spectral bands of red light provides characteristic curves for dose interpretations with approximately ±5% reproducibility.

Print-out of heteropolyacids — Silicotungstic, phosphotungstic, or phosphomolybdic acid in gelatin or plastic is darkened permanently by irradiation (10^4 to 10^7 rads; 10^2 to 10^5 Gy) due to the formation of nucleates of heavy metal.[164,165] The high atomic-number constituents of the print-out materials generally cause marked energy dependence of response relative to that of food.

Trans-cis isomerization of stilbene — Polystyrene films containing *trans*-stilbene undergo a lowering of optical density with analysis at 324 nm wavelength due to radiation-induced isomerization to *cis*-stilbene (10^5 to 10^8 rads; 10^3 to 10^6 Gy). The response is not dose-rate dependent.[166]

Phosphor degradation — The photo-stimulated emission of organic phosphors, such as anthracene, biphenyl, and stilbene is diminished due to irradiation to megarad doses.[109,167-169]

Formation of malondialdehyde from irradiated polyhydroxy compounds — Irradiation of aqueous solutions of sugar or mannitol containing 0.1 *M* NaOH results in the formation of a red color with the addition of a pH indicator.[170,171] Absorbed doses of 10^5 to 10^7 rads (10^3 to 10^5 Gy) can thus be determined by spectrophotometry at 555 nm wavelength.

Bleaching of dyes — Solid films, such as dyed cellophane,[172-174] dyed cellulose acetate (Cinemoid®),[175] or dyed polyvinyl alcohol[176-178] can be used for measuring absorbed doses of 1 to 10 Mrads (10 to 100 kGy). The response is somewhat nonlinear, with rather poor reproducibility. The response also varies strongly with temperature during irradiation, as the temperature exceeds room temperature (20°C).

Liquid dye solutions, such as aqueous methylene blue[179,180] or aqueous xylenol orange[181] are useful for measuring doses of 10^3 to 10^6 rads (10 to 10^4 Gy) by spectrophotometric analysis of loss of color due to radiolytic bleaching of the dye. Unlike radiolytic dye formation from radiochromic dye precursors, i.e., triphenylmethane cyanides (see Section IV.B), dye bleaching usually is dose-rate dependent.

Chemical dosimetry for low doses — Several chemical systems have been proposed for measuring absorbed doses of less than 1000 rad (10Gy).[182,183] Using radioactive iron (^{59}Fe) tracer analysis in combination with ferrous sulfate solutions is one successful method. It involves application of either solvent extraction (iso-amylalcohol) of

Fe^{3+} complexed with KSCN or isolation of Fe^{3+} by a XRO $(H_3PO_4)_2$ ion-exchange column.[184] Gupta and co-workers have also shown that it is possible to read doses from 10 to 10^4 rad (0.1 to 100 Gy) by combining aqueous xylenol orange dye and benzoic acid with ferrous sulfate.[185-187] In this case, irradiation increases the absorbance at 540 nm wavelength because of the oxidation of Fe^{2+} ions to Fe^{3+} ions, which complex with the dye. Photostimulated fluorescence due to prior irradiation of aqueous solution of terephthalic acid plus 2-hydroxyterephthalic acid[182,188] is another chemical method for dosimetry from approximately 30 to 1000 rad (0.3 to 10 Gy).

Indicator dyes with halogenated hydrocarbons — The production of acid due to the irradiation of halogenated hydrocarbons lends itself to the use of dye indicators of pH change. Two-phase liquid systems are generally based on aqueous solution of chloroform or tetrachloroethylene stabilized by resorcinol, to which an indicator dye, such as bromocresol purple or chlorophenol red, is added by shaking.[189-191] By using spectrophotometry at a given wavelength these systems can be used for determining absorbed doses of ∼50 to 10^6 rad (0.5 to 10^4 Gy), depending on concentrations of the ingredients. Single-phase dosimeter solutions with essentially the same ingredients can also be used with somewhat diminished sensitivity. Aqueous solutions or gels of chloralhydrate containing an indicator dye (e.g., methyl orange) show a change to a deep red color when irradiated to kilorad doses.[192-195] General problems with these systems are oxygen, temperature, and rate dependence of response.

Tetra-azolium chloride — Triphenyl tetra-azolium chloride in aqueous solutions or dissolved in polyvinyl alcohol films responds linearly to radiation doses between 10^5 and 10^7 rad (10^3 to 10^5 Gy), depending on the thickness of the dosimeter.[82,196-198] The method of readout is spectrophotometry at 410 nm wavelength. These colorless dosimeters become violet upon irradiation and are only slightly dose-rate dependent, but the response varies greatly with temperature during irradiation.

Degradation of polymers (viscometry) — As in the case of polyisobutylene (see Section V.J), the measurement of decrease in viscosity of polymer solutions (e.g., polyacrylamide in aqueous solutions) is useful for measuring absorbed doses from 10^2 to 10^5 rad (1 to 10^3 Gy).[140,199-203] This radiation effect is nonlinear with dose and is sensitive to the presence or absence of oxygen and to batch differences.

Miscellaneous plastic films (spectrophotometry) — Various plastics show changes in ultraviolet absorption characteristics due to irradiation and have been used in dosimetry. Some of these are cellulose di- or triacetate,[204-207] polyethylene terephthalate,[208] melamine plastic,[209] polycarbonate,[210] and polyvinylidine chloride.[106]

Changes in melting point of plastics — Radiation degradation of Penton (poly-3,3-bis-chloromethyl-oxetane) causes changes in the melting point and optical absorbance, both of which can be used as a measure of absorbed dose in the megarad range.[211] Radiation-induced changes in the melt index of a number of plastics (e.g., polyethylene) can also be used for dosimetry of large doses.

VI. DOSIMETRY APPLIED TO FOOD IRRADIATION

A. Aims

The three main purposes of dosimetry in food irradiation are (1) *research* — to determine dose levels and dose distributions in early radiation studies of a given food preservation process; (2) *commissioning* — to ascertain and set process irradiation parameters, such as residence time in the irradiator, dwell time in a shuffle- and dwell-irradiator, transit doses plus principal doses, and conveyor speeds in order to effect a given process (i.e., to attain prescribed values of D_{min} and $U = D_{max}/D_{min}$ for each food item of interest); (3) *quality control* — to supply dose value sampling within items and among different items in a process run and to provide sufficient data for measurement assurance that the food has been irradiated within specifications. The last of these is mainly important where there are heterogeneous products or disparities in bulk density throughout a process run.

B. Determinations of Dose Distributions

1. The Use of Thin-Film Dosimeters

A thin-film dosimeter may be inserted at different places in an irradiated medium in order to measure absorbed dose or the distribution of absorbed dose in the medium.[87,212-215] Cavity theory must be applied properly in order to convert the radiation response of the calibrated thin-film dosimeter to a meaningful interpretation of absorbed dose in the main absorbing medium.[87,216] Conditions for accomplishing this are the following: (1) the dosimeter "cavity" (e.g., a thin film) must be small relative to the range of secondary electrons, i.e., interactions in the dosimeter producing secondary electrons must be negligible relative to those in the surrounding material; (2) the electron spectrum must be essentially undisturbed by the presence of such a thin dosimeter; and (3) the photon and electron fluence and energy loss gradients must be relatively uniform and continuous in regions close to the "cavity".

With most ionizing photon radiations used in food irradiation (i.e., photon and electron energies of hundreds of kilovolts or greater), some of the thin plastic film dosimeters discussed previously are sufficiently nondisruptive to satisfy the most important cavity-theory requirements. The absorbed dose in a medium of interest, D_m, can be determined from dose readings of a calibrated film dosimeter, D_f, inserted in that medium:[216]

$$D_m = \frac{1}{\bar{s}_{fm}} D_f$$

where

$$\bar{s}_{fm} = E_o \Big/ \int_0^{E_o} \frac{dE}{s_{fm}}$$

and

$$s_{fm} = \frac{\left[\dfrac{1}{\rho}\dfrac{dE}{dx}\right]_f}{\left[\dfrac{1}{\rho}\dfrac{dE}{dx}\right]_m}$$

ρ being the density of each material in g/cm^3, E_o the highest electron energy in MeV, and dE/dx the electron collision stopping power of each material in MeV · cm^2·g^{-1}. Assuming an essentially uniform distribution of secondary electrons, as when cavity-theory conditions[87,216] are approximately satisfied, the dose in the medium of interest can be calculated as follows:

$$D_m \approx \frac{\left[\dfrac{1}{\rho}\dfrac{dE}{dx}\right]_m}{\left[\dfrac{1}{\rho}\dfrac{dE}{dx}\right]_f} D_f$$

where the values of stopping power are averaged over the estimated electron spectrum. This relation is also used for determining dose in a given material containing a film dosimeter irradiated with a fast electron beam, where it is possible to evaluate the approximate electron spectrum at the position of the dosimeter and accordingly weight the values of stopping power over that spectrum.[83,87]

If the film dosimeter irradiated by ionizing photons (i.e., X- and gamma rays) is surrounded by a material of essentially the same density and atomic constituency by weight and if dose values must be interpreted in a material different from the dosimeter material and its surroundings, then the dose can be calculated approximately as follows from the dosimeter reading:

$$D_m \approx \frac{(\overline{\mu_{en}/\rho})_m}{(\overline{\mu_{en}/\rho})_f} .$$

where μ_{en}/ϱ is the mass energy absorption coefficient for ionizing photons absorbed in the appropriate material, averaged over the approximate photon spectrum.

For a number of dosimeter materials, tabulations of

$$\text{ratios of } \left(\frac{\mu}{\rho}\right)^{en}_{water} \Big/ \left(\frac{\mu}{\rho}\right)^{en}_{material} \text{ and } \left[\frac{1}{\rho}\ \frac{dE}{dx}\right]_{water} \Big/ \left[\frac{1}{\rho}\ \frac{dE}{dx}\right]_{material} \text{ over spectral}$$

energies normally used in food irradiations are given in Tables 2 and 3, respectively.

Comparisons of experimental measurements with theoretical calculations of depth-dose in various materials have shown that properly calibrated thin dosimeters, e.g., radiochromic dye films (see Section IV.B), may be used to provide accurate dose distribution data in irradiated media, even close to interfaces of different materials.[15,84,86,88,215] The film dosimeter response (e.g., optical absorbance change vs. absorbed dose in a given absorber) is first calibrated calorimetrically.[26,81,87] Then by using ratios of absorption coefficients or stopping powers, as prescribed by cavity-theory considerations, the absorbed dose in a film material may be specified. Experience has shown that even in highly hydrogenous materials or heavy metals, properly calibrated thin dosimeters give faithful readings of absorbed dose or dose distributions, when oriented either as single films imbedded in an irradiated medium or as stacks of films adjacent to other absorbers (see Figures 12 and 13). It should be pointed out that, in the calibration of dosimeters, the shape and size of the dosimeters relative to the radiation orientation (i.e., monodirectional or isotropic) affects the dose interpretation somewhat. This is true even for dosimeters surrounded by material thick enough to approximate electron equilibrium[3] and irradiated with gamma rays from a cobalt-60 source. Examples of typical discrepancies are shown as ratios of dose readings in Figure 14.

Other more serious discrepancies occur due to excursions of the dose close to interfaces of different materials. These sharp dose gradients are difficult to calculate and difficult to measure, but by using correct dosimetry with high spatial resolution, it is possible to obtain useful data close to interfaces.[15,27,86,218,220-222] Miller[224] for example, has measured absorbed dose at interfaces by means of thin-film calorimetry. Calibrated thin-film dosimeter stacks also provide detailed dose distribution data close to interfaces.[15,74,87,89] It is necessary to have this concept in mind when considering the effect of high atomic number surroundings, such as glass walls, on the dose interpretations by aqueous dosimeter solutions held in ampules.[225,226] Without appropriate correction factors, this effect can contribute appreciable systematic errors to the dose interpretations by liquid chemical dosimeters.

Table 2
RATIO OF PHOTON MASS ENERGY ABSORPTION COEFFICIENTS OF WATER TO THOSE IN DIFFERENT SUBSTANCES AND DOSIMETER MATERIALS[117]

$$\left(\mu/\rho\right)^{en}_{water} \Big/ \left(\mu/\rho\right)^{en}_{material}$$

Photon energy (MeV)	H	C	N	O	Al	Fe	Cu	Pb
0.05	1.53	1.76	1.31	0.958	0.225	0.0253	0.0186	0.00633
0.1	0.624	1.18	1.14	1.08	0.658	0.116	0.0841	0.0111
0.15	0.574	1.13	1.13	1.10	0.966	0.328	0.260	0.0240
0.2	0.565	1.12	1.12	1.11	1.08	0.600	0.497	0.0472
0.3	0.560	1.11	1.11	1.11	1.13	0.952	0.862	0.123
0.4	0.560	1.11	1.11	1.11	1.14	1.06	1.02	0.229
0.5	0.556	1.11	1.11	1.11	1.15	1.12	1.10	0.347
0.6	0.560	1.12	1.12	1.11	1.15	1.15	1.15	0.463
0.05—0.66[a]	0.575	1.13	1.12	1.11	1.12	1.02	1.00	0.392
0.66[a]	0.561	1.12	1.12	1.11	1.16	1.16	1.16	0.525
0.8	0.560	1.11	1.11	1.11	1.16	1.18	1.18	0.667
1.0	0.557	1.11	1.11	1.11	1.15	1.18	1.20	0.820
0.05—1.25[a]	0.573	1.13	1.12	1.11	1.11	1.07	1.07	0.762
1.25[a]	0.557	1.11	1.11	1.11	1.15	1.18	1.20	0.950
1.5	0.556	1.11	1.11	1.11	1.15	1.19	1.21	1.04
2.0	0.560	1.11	1.11	1.11	1.15	1.18	1.20	1.08
3.0	0.570	1.11	1.11	1.10	1.12	1.11	1.12	0.970
4.0	0.585	1.11	1.11	1.10	1.10	1.04	1.03	0.841
5.0	0.602	1.12	1.10	1.09	1.07	0.965	0.955	0.737
6.0	0.621	1.12	1.10	1.08	1.05	0.904	0.892	0.662
8.0	0.659	1.13	1.10	1.07	0.988	0.814	0.794	0.565
10.0	0.697	1.14	1.09	1.06	0.952	0.751	0.730	0.506

	Muscle	Compact bone	Fricke dosimeter	Polysterene $(C_8H_8)n$	Perspex® $(C_5H_8)n$	Polyethylene $(C_2H_4)n$	LiF	Glass[e]	PVC (C_2H_3Cl)
0.05	0.961	0.258	0.908	1.74	1.38	1.72	0.925	0.340	0.169
0.1	0.992	0.657	0.981	1.11	1.07	1.05	1.13	0.782	0.549
0.15	1.01	0.905	1.00	1.05	1.04	0.991	1.18	1.01	0.873
0.2	1.01	0.986	1.00	1.04	1.03	0.980	1.19	1.08	1.00
0.3	1.01	1.03	1.00	1.03	1.03	0.975	1.20	1.10	1.06
0.4	1.01	1.04	1.00	1.03	1.03	0.974	1.20	1.11	1.08
0.5	1.01	1.04	1.00	1.03	1.02	0.973	1.20	1.11	1.08
0.6	1.01	1.05	1.00	1.03	1.03	0.973	1.20	1.12	1.09
0.05—0.66[a]	1.01	1.02	1.00	1.04	1.04	0.985	1.19	1.09	1.04
0.66[b]	1.01	1.05	1.00	1.03	1.03	0.973	1.20	1.12	1.09
0.8	1.01	1.05	1.00	1.04	1.03	0.973	1.20	1.12	1.09
1.0	1.01	1.05	1.00	1.03	1.03	0.972	1.20	1.12	1.08
0.05—1.25[c]	1.01	1.02	1.00	1.04	1.04	0.983	1.19	1.09	1.04
1.25[d]	1.01	1.05	1.00	1.03	1.03	0.972	1.20	1.12	1.08
1.5	1.01	1.04	1.00	1.03	1.03	0.973	1.19	1.12	1.08
2.0	1.01	1.04	1.00	1.03	1.03	0.973	1.20	1.12	1.07
3.0	1.01	1.03	1.00	1.04	1.03	0.980	1.19	1.10	1.07
4.0	1.01	1.03	1.00	1.04	1.04	0.988	1.19	1.08	1.05
5.0	1.01	1.02	1.00	1.05	1.04	0.998	1.19	1.07	1.03
6.0	1.01	1.01	1.00	1.05	1.04	1.01	1.18	1.05	1.00
8.0	1.01	0.994	1.00	1.07	1.05	1.02	1.18	1.02	0.993
10.0	1.01	0.987	1.00	1.08	1.06	1.04	1.17	1.00	0.990

[a] Typical degraded cesium-137 γ-ray spectrum in water.[3]

[b] Primary cesium-137 γ-ray energy.

[c] Typical degraded cobalt-60 γ-ray spectrum in water.[3]

[d] Primary average cobalt-60 γ-ray energy.

[e] Typical Pyrex® glass:[11] 80.7% Si_2O, 12.9% B_2O_3, 3.8% Na_2O, 2.2% Al_2O_3, 0.4% K_2O.

Table 3

RATIO OF MASS COLLISION STOPPING POWER FOR ELECTRONS IN WATER RELATIVE TO THAT IN DIFFERENT SUBSTANCES AND DOSIMETER MATERIALS[318,319]

$$\left[\frac{1}{\delta}\ \frac{dE}{dx}\right]_{water} \Big/ \left[\frac{1}{\delta}\ \frac{dE}{dx}\right]_{material}$$

Electron energy (MeV)	H	C	N	O	Al	Fe	Cu	Pb
0.05	0.472	1.14	1.16	1.16	1.34	1.53	1.59	2.25
0.1	0.479	1.14	1.15	1.16	1.33	1.50	1.55	2.13
0.15	0.483	1.14	1.15	1.16	1.32	1.49	1.54	2.08
0.2	0.485	1.14	1.15	1.15	1.31	1.48	1.52	2.05
0.3	0.487	1.14	1.15	1.15	1.31	1.47	1.51	2.00
0.4	0.489	1.15	1.14	1.15	1.30	1.46	1.51	1.97
0.5	0.490	1.15	1.14	1.15	1.30	1.46	1.50	1.95
0.6	0.491	1.15	1.14	1.15	1.30	1.45	1.50	1.93
0.7	0.491	1.15	1.14	1.14	1.29	1.45	1.49	1.92
0.8	0.491	1.15	1.13	1.14	1.29	1.44	1.49	1.90
0.9	0.491	1.16	1.13	1.14	1.29	1.44	1.49	1.89
1.0	0.489	1.16	1.12	1.13	1.28	1.43	1.48	1.88
2.0	0.483	1.16	1.10	1.10	1.26	1.41	1.45	1.80
3.0	0.478	1.16	1.08	1.08	1.25	1.39	1.44	1.77
4.0	0.475	1.16	1.07	1.07	1.24	1.38	1.43	1.74
5.0	0.472	1.16	1.06	1.06	1.24	1.38	1.42	1.73
6.0	0.469	1.16	1.05	1.05	1.24	1.37	1.42	1.71
7.0	0.467	1.16	1.04	1.04	1.24	1.37	1.41	1.70
8.0	0.465	1.16	1.03	1.04	1.24	1.37	1.41	1.70
9.0	0.464	1.16	1.03	1.03	1.24	1.37	1.41	1.70
10.0	0.462	1.16	1.02	1.03	1.24	1.37	1.41	1.69

Electron energy (MeV)	Muscle	Compact bone	Fricke dosimeter	Polystyrene $(C_8H_8)_n$	Perspex® $(C_5H_8O_2)_n$	Polyethylene $(C_2H_4)_n$	LiF	Glass*	PVC
0.05	1.01	1.09	1.01	1.03	1.03	0.948	1.26	1.26	1.24
0.1	1.01	1.09	1.01	1.03	1.03	0.951	1.25	1.24	1.23
0.15	1.02	1.08	1.01	1.03	1.03	0.952	1.25	1.24	1.22
0.2	1.02	1.08	1.01	1.03	1.03	0.953	1.25	1.24	1.22
0.3	1.02	1.08	1.01	1.03	1.03	0.956	1.25	1.23	1.21
0.4	1.03	1.08	1.00	1.03	1.04	0.960	1.25	1.23	1.21
0.5	1.03	1.08	1.00	1.04	1.04	0.963	1.25	1.23	1.21
0.6	1.03	1.08	1.00	1.04	1.04	0.965	1.25	1.23	1.21
0.7	1.03	1.08	1.00	1.04	1.04	0.967	1.25	1.22	1.21
0.8	1.03	1.08	1.00	1.04	1.05	0.969	1.25	1.22	1.20
0.9	1.03	1.08	1.00	1.04	1.05	0.970	1.25	1.22	1.20
1.0	1.03	1.08	1.00	1.04	1.05	0.971	1.25	1.21	1.20
2.0	1.03	1.08	1.00	1.05	1.05	0.977	1.25	1.19	1.17
3.0	1.02	1.08	1.00	1.05	1.06	0.981	1.26	1.18	1.16
4.0	1.02	1.08	1.00	1.05	1.06	0.982	1.26	1.17	1.15
5.0	1.02	1.08	1.00	1.05	1.06	0.983	1.26	1.16	1.14
6.0	1.02	1.08	1.00	1.05	1.06	0.984	1.26	1.16	1.13
7.0	1.02	1.08	1.00	1.05	1.06	0.985	1.27	1.15	1.13
8.0	1.02	1.08	1.00	1.05	1.06	0.986	1.27	1.14	1.13
9.0	1.02	1.08	1.00	1.05	1.06	0.987	1.27	1.14	1.12
10.0	1.02	1.08	1.00	1.06	1.06	0.988	1.27	1.14	1.12

* Typical Pyrex® glass:[16] 80.7% Si_2O, 12.9% B_2O_3; 3.8% Na_2O, 2.2% Al_2O_3, 0.4% K_2O.

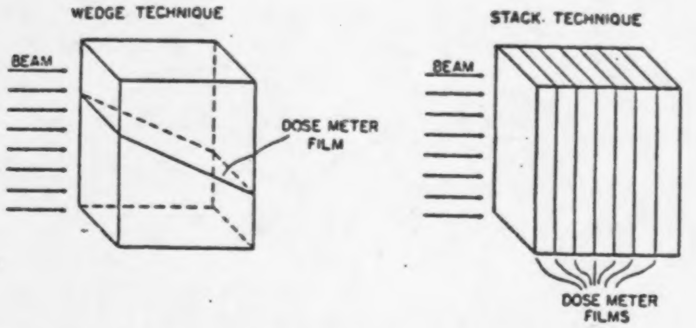

FIGURE 12. The positioning of thin dosimeter films in an irradiated medium in order to determine the absorbed dose as a function of penetration depth, by two orientation techniques: wedge (left) and stack (right).

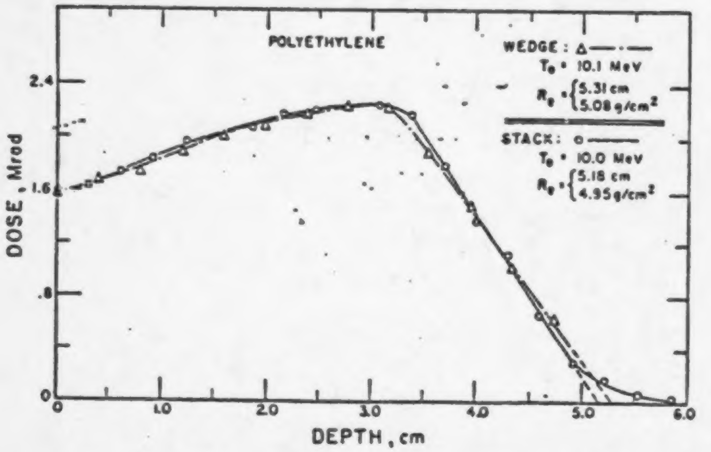

FIGURE 13. Depth-dose curve for a broad 10-MeV electron beam incident perpendicularly on a semi-infinite polyethylene slab containing thin radiochromic dosimeter film, either in a stack or wedge technique (see Figure 12). The values of incident electron energy (T_0) can be determined from the values of the extrapolated range (R_p).[127]

2. *The Placement of Dosimeters*

For food irradiation containers uniformly loaded with a relatively homogeneous product and irradiated by an essentially monoenergetic, monodirectional radiation beam, the approximate positions of D_{min} and D_{max} are relatively easy to determine.[127] This determination might be based either on *in situ* measurements or on documented experimental or theoretical depth-dose curves for photon or electron irradiation.[1,3] On the other hand, in the more usual case of broad spectral distributions of radiation diffusely incident on heterogeneous product, it is necessary in most situations to determine experimentally the locations and values of D_{min} and D_{max} for a given set of process parameters. Exceptions to this are calculations of these values for large plaque sources and uniform products.[228-230] Usually, however, the placement of large numbers of dosimeters throughout the product or a container holding simulated prod-

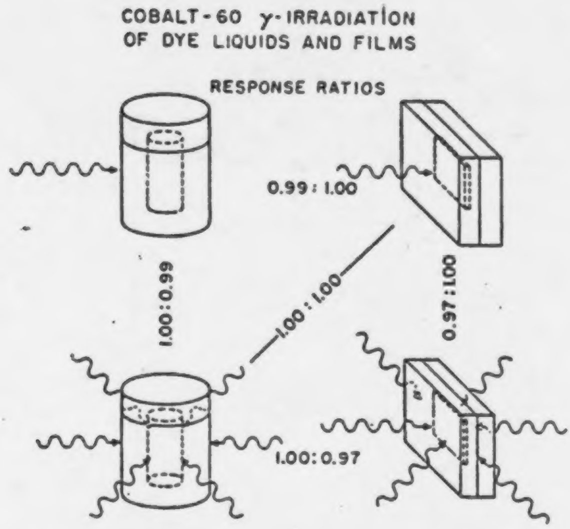

FIGURE 14. Ratios of dose interpretations of different irradiation geometries for dosimeters held in plastic shells having a thickness approximately equivalent to electron equilibrium (0.5 cm) and irradiated with cobalt-60 gamma rays. Left: cylindrical dosimeters; Right: thin-film dose meters; Top: monodirectional parallel beam; Bottom: isotropic radiation field.

uct is the only way to accomplish dose mapping. An example of such locations is shown in Figure 15. There are also apt to be moderate variations of product bulk density and degree of heterogeneity within one production run. Therefore, for commissioning a given process, it is recommended to make a determination of mean values of D_{min} and D_{max} as well as their standard deviations with specified confidence limits and tolerance values. This use of dosimetry for commissioning a radiation process will be discussed in Section VI.C.

In some highly heterogeneous products, where air cavities or high atomic number materials are adjacent to foodstuffs, it may be necessary to place small dosimeters close to these interfaces in order to resolve dose distribution anomalies or discontinuities. Irradiations with photons or electrons are known to produce marked dose gradients close to such interfaces. An example is illustrated in Figure 16, for a radiochromic dosimeter film strip held horizontal across gamma-ray irradiated compacted foamed plastic layers (bulk density 0.25 g/cm^3) filling a stainless steel can.[131] Properly calibrated thin-film dosimeters of this type (see Section IV.B) placed at interface sites can usually supply accurate readings of absorbed dose in a thin layer having radiation absorption properties similar to low atomic number biological tissue. This is a convenient way to determine the extent of sharp gradients in radiation energy deposition.

Figure 17 shows the placement of thin dosimeters in a heterogeneous medium (concentric plastic cylinders in an insulated box) irradiated along with homogeneous product of approximately the same bulk density being sterilized in a large shuffle-and-dwell cobalt-60 irradiator. By using radiochromic dye films previously calibrated under electron equilibrium, it was possible to measure absorbed doses at the different surface locations. Table 4 lists the dose readings at the indicated locations in Figure 17, all of which are at plastic-air interfaces. The highest readings are on the outer layers, as would be expected.

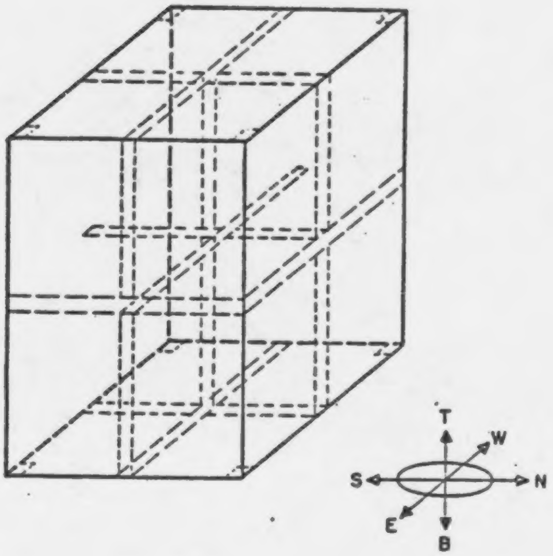

FIGURE 15. A food item box with positions of radiochromic dye-film dosimeter strips. Small pieces of dosimeter film are also placed in the eight corners of the box, which moves in an east-to-west direction in passages by the vertical ^{60}Co gamma-ray source plaques and then is turned 180° and irradiated from the opposite side. T and B represent top and bottom, respectively.[41] (From International Atomic Energy Agency Publ. No. SM222/9. With permission.)

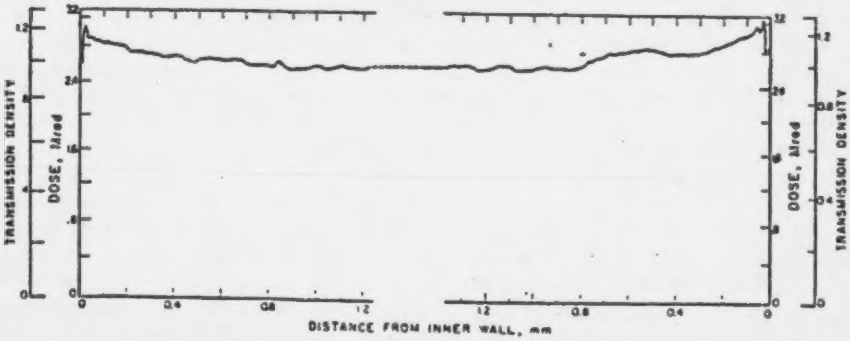

FIGURE 16. Microdensitometer scan of a radiochromic image of dose distribution near the inner wall of a stainless steel cylindrical can containing compacted styrofoam (bulk density 0.25 g/cm^3) and irradiated with cylindrical isotropy by cobalt-60 gamma rays.

These films obey cavity-theory requirements, are mainly dose rate independent, and have radiation absorption characteristics similar to those of water or many biological tissues for photons and electrons over the broad spectrum used in food irradiation. Therefore, they are ideal for determining doses at interfaces and detailed dose profiles in heterogeneous media.

Using a scanned beam of 10-MeV electrons incident on a slab of beef muscle or

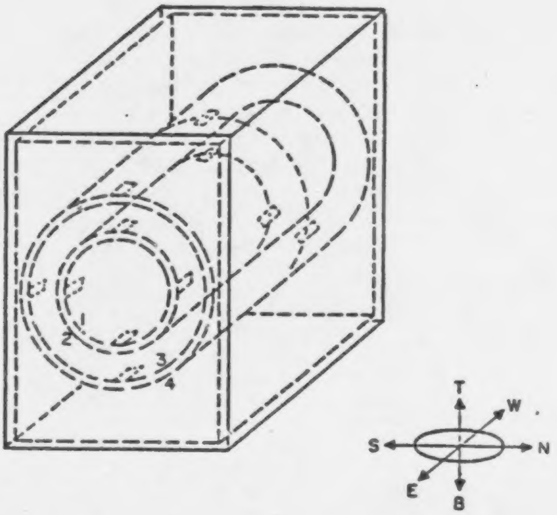

FIGURE 17. A food item box insulated by cardboard and containing concentric cylinders (length 42 cm) of polypropylene. Inner cylinder: thickness 0.53 cm and outer diameter 11.2 cm; outer cylinder: thickness 0.68 cm and outer diameter 19.0 cm. The box was irradiated along with uniformly loaded item boxes by gamma rays from two sides, south and north, using a large production stationary cobalt-60 source plaque. The cylinder surfaces are indicated by numbers 1, 2, 3, and 4. Dosimeter film locations are indicated in a bisecting plane perpendicular to the cylinder axes and at the east end of the cylinders.

plastic layer 10 cm wide and about 3 cm in depth, it is possible to place dosimeter films at various depths and measure three distinct forms of interface dose excursions close to air-muscle or air-plastic interfaces:[84,237]

1. Figure 18 shows the central depth-dose curve in two stacked beef muscle slabs having a total thickness of 3.2 g/cm^2. Each material was packaged in a laminated aluminum polyethylene pouch during irradiation.
2. Figure 19 shows the lateral dose distribution in a radiochromic film held perpendicular to the electron beam at an intermediate depth in the irradiated pouches. Here the effect of voids or air cavities in the beef muscle reduces attenuation of electrons, thus causing an increase in absorbed dose at certain locations, with a decrease at edges near the air interface where there is less side-scatter of radiation.
3. Figure 20 shows details of the variation of dose close to the side edge at various depths in beef muscle. The curves are shown in terms of relative dose, that is, relative to the dose reading close to the air-muscle interface at the front surface.

3. The Interpretation of Dose Distribution Data

In food irradiation dosimetry, it is not always necessary to determine precisely the dose distribution throughout the product. One must, however, determine the locations of D_{min} and D_{max} in a production run. This can be accomplished by making dose mapping studies, with calibrated dosimeters placed throughout a typical product package (or "dummy" product). This package is to be surrounded by other product (or "dummy" product) as in a normal process run. Using these data, it is then possible to make a statistical analysis of minimum and maximum doses by placing dosimeters as needed at locations of D_{min} and D_{max} in a number of product boxes during the radiation process. Such procedures are required for commissioning a process and setting beam parameters as will be discussed in Section VI.C.

Table 4
AVERAGE ABSORBED DOSE READINGS AT STRATEGIC LOCATIONS IN AN INHOMOGENEOUS ABSORBER IRRADIATED WITH GAMMA RADIATION FROM A ^{60}CO PLAQUE SOURCE (SEE FIGURE 17 FOR LOCATIONS)

Cylindrical surface	Plane	Orientation	Absorbed dose readings (Mrad)
1	East	Top, bottom	2.70
1	East	South, North	2.79
1	Center	Top, bottom	2.74
1	Center	South, North	2.80
2	East	Top, bottom	2.76
2	East	South, North	2.81
2	Center	Top, bottom	2.77
2	Center	South, North	2.81
3	East	Top, bottom	2.77
3	East	South, North	2.78
3	Center	Top, bottom	2.87
3	Center	South, North	2.86
4	East	Top, bottom	2.75
4	East	South, North	2.82
4	Center	Top, bottom	2.90
4	Center	South, North	2.95

The determination of the absolute levels of absorbed dose in the food product is an important requirement not only in establishing the process, but also in maintaining quality control. Accurate measurements are used as vital evidence in food irradiation petitions to regulatory bodies. There must be meaningful dosimetry in the research that leads to a process, in the commissioning of the process, and in maintaining process control. Even after process parameters have been set (e.g., source and product configuration, conveyor speed, dwell time, bulk density, etc.), it may be necessary to present correct dosimetry data and record keeping as important prerequisites for product release.

The approximate regions of D_{min} and D_{max} are shown in Figure 21, for a relatively homogeneous product box irradiated from two sides by a ^{60}Co plaque source.[3] Actually the dose distribution along these regions is nonuniform and, in fact, depends on the size of the source plaque relative to the product size. Figure 22 shows the approximate dose distribution along the centerlines of the outside plane (P1-P2) and the midplane (P5-P9), for two-sided irradiation by two sizes of source plaques.[228,230] These are planes parallel to the source plaque which, in one case, is the same size as the product cross-section and in the other case, is 26 cm longer and wider. Figure 23 shows the approximate dose distributions along diagonal lines, P11-P12 and P13-P14 of the outside and midplanes, respectively (see Figure 21), and for no overlap of the source plaque and for 13 cm overlap.[230]

Electron beam irradiations of food products can be made either from one side or from two sides. The data in Figures 13 and 18 have shown that even with one-sided irradiation the dose is relatively uniform up to a certain depth. The approximate regions of D_{min} and D_{max} for a one-sided electron beam irradiation of a relatively homogeneous product are illustrated in Figure 24.[3] These extreme dose regions are displayed in Figure 25 for a two-sided electron beam irradiation of the same product.[3] Actually these positions can drift somewhat depending on irradiation geometry and depth-dose overlap.

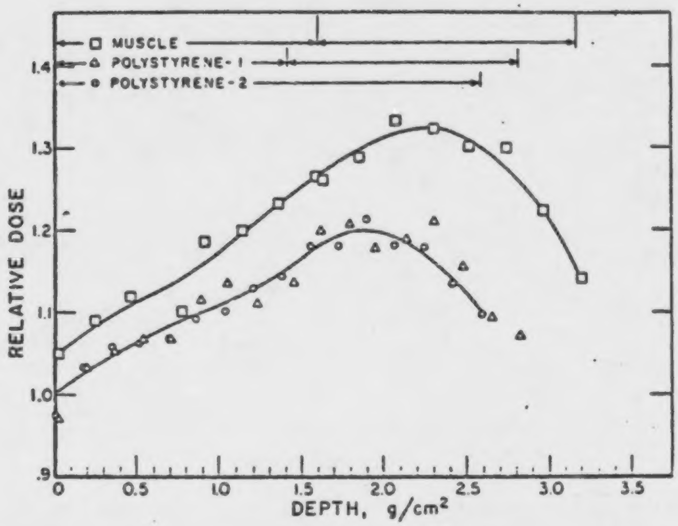

FIGURE 18. Depth-dose distribution in twin stacked packages of beef muscle or polystyrene irradiated with 10-MeV electrons, as determined with radiochromic film dosimeters. Arrows at the top indicate the two package thicknesses of each material. Each total thickness is less than the electron range. All dose values on the ordinate were normalized to the entrance dose for the polystyrene layers.[44]

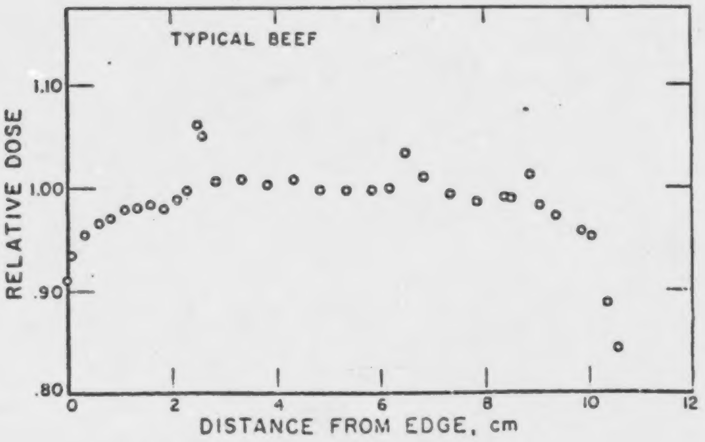

FIGURE 19. Gross lateral dose distributions in beef package 10 cm long and 1.6 cm thick (see Figure 18) irradiated with 10-MeV electrons. The dose readings were made at various positions across a radiochromic dye film that was situated perpendicular to the electron beam direction in a midplane of the package. The dose values were normalized to the average measured values of dose in the center portion of the package.[44]

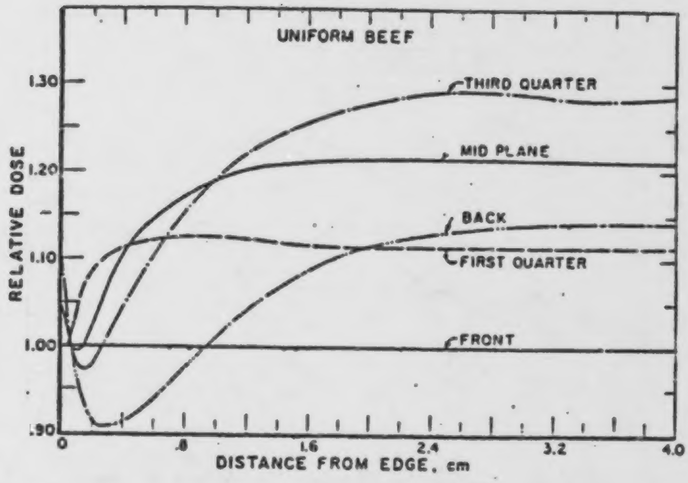

FIGURE 20. Detailed lateral dose distributions at various depths and close to the side edge of a beef package (see Figures 18 and 19) irradiated with 10-MeV electrons, as determined with strips of radiochromic film dosimeters. The dose values were normalized to the dose at the front surface of the package situated perpendicular to the beam direction.[44]

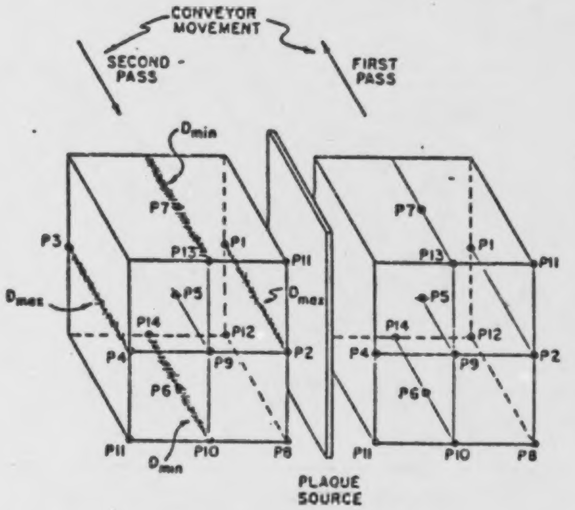
CONVEYOR MOVEMENT
SECOND - PASS
FIRST PASS
D_{min}
D_{max}
D_{max}
D_{min}
P1
P2
P3
P4
P5
P6
P7
P8
P9
P10
P11
P12
P13
P14
PLAQUE SOURCE

FIGURE 21. Two single-direction passes of a rectangular food item, once on each side of a stationary cobalt-60 source plaque. Approximate regions of D_{min} and D_{max} after the second pass are indicated by hatching.[1]

C. Commissioning and Quality Control

1. Types of Radiation Processes

Industrial processes using ionizing photon and electron sources can be divided into two main categories — *batch processes* and *continuous processes.*[3]

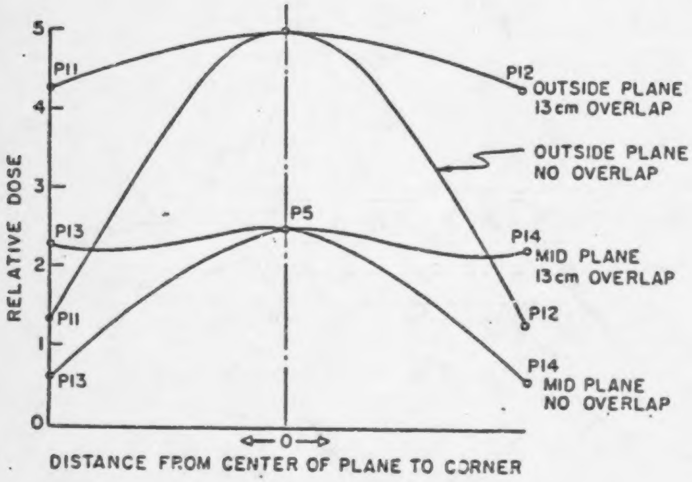

FIGURE 22. Relative dose distributions along lines from the center position of outside and midplanes to the middle positions of the edges of the planes of a uniformly loaded rectangular package. It is irradiated with gamma rays from both sides, either by a stationary cobalt-60 plaque source with no overlap or by a stationary plaque source with a 13-cm overlap of the package. The positions of the center and edge reference points are indicated (see Figure 21).[119]

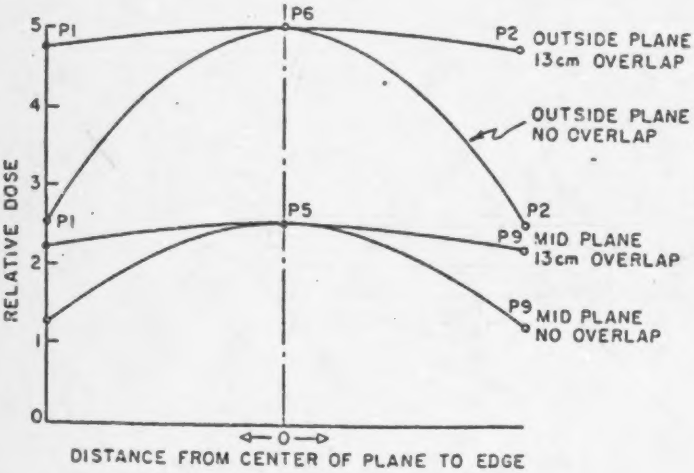

FIGURE 23. Relative dose distributions along diagonals of outside and midplanes of a uniformly loaded rectangular package. It is irradiated with gamma rays from both sides, either by a stationary cobalt-60 plaque source with no overlap or by a stationary plaque source with a 13-cm overlap of the package. The positions of center and corner reference points are indicated (see Figure 21).[119]

Batch processes are those in which the food items are irradiated in lots, each lot ing placed in the irradiation chamber or carrousel and removed before the next lot inserted.

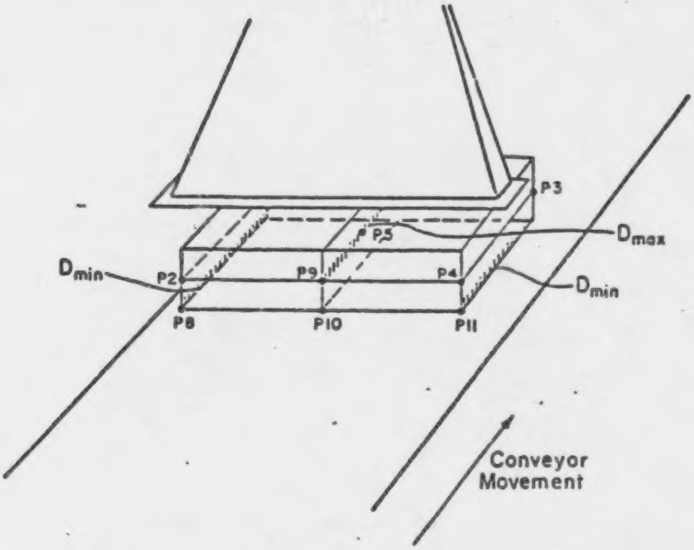
P3
P5
Dmax
Dmin
P2
P9
P4
Dmin
P8
P10
P11
Conveyor
Movement

FIGURE 24. Typical arrangement for single-pass, single-direction electron beam irradiation of a rectangular package, with approximate regions of D_{max} and D_{min} indicated by hatching.[3] The electron beam scans the package from above. (From International Atomic Energy Agency, Tech. Rep. Ser. 178, 65. With permission.)

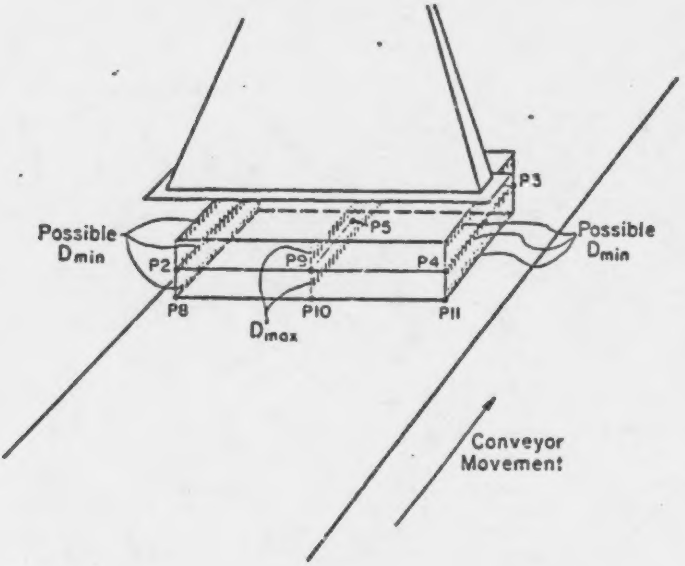
P3
Possible
Dmin
P5
Possible
Dmin
P2
P9
P4
P8
P10
P11
Dmax
Conveyor
Movement

FIGURE 25. Typical arrangement for the second pass of a two-pass, two-sided, single-direction electron beam irradiation of a rectangular package, with approximate regions of D_{max} and D_{min} indicated by hatching.[3] (From International Atomic Energy Agency, Tech. Rep. Ser. 178, 66. With permission.)

Continuous processes are those in which the items are conveyed continuously through an exposure chamber past a radionuclide source or through a scanned electron beam. Most large commercial irradiations using radionuclides or machine sources are of the continuous type. For control of material flow, a continuous process can be operated in a batch mode wherein discrete numbers of food containers (or *items*) are identified individually according to their origins or components.[233] In this case, the process operates in a continuous fashion.

There are also situations in which continuous processes are made to operate in a discontinuous mode. For example, discontinuous operation is used when different item lots require different absorbed doses or when, for reasons of varying energy absorption parameters of items, process operating conditions must be adjusted. In the latter case, however, each quantity of item lots processed under a given set of process parameters constitutes a discrete batch.

2. Process Aims

The main goal of food irradiation is to cause prescribed effects in the food by deposition of ionizing radiation energy. These changes are dependent on absorbed dose. Consequently, the dose is usually the parameter that is measured in order to verify the efficacy of the process or quality of the processed goods.

For a wide variety of foods, experience has established certain lower limits of dose (D_{min}^{limit}), below which the desired radiation effect is not achieved. Upper dose limits (D_{max}^{limit}) are also specified, as determined by the effect of excessive irradiation on the food quality of the product and/or the economics of the process.

3. Control and Documentation

The degree of control of deposited radiation energy and its documentation are determined by: (1) the specification of the allowable dose limits for each product; (2) the requirements of regulatory agencies; and (3) the relative economics in terms of the costs of process monitoring and control vs. the risks of production and release of unacceptable goods. Documentation is achieved by meticulous dosimetry data keeping and evidence of fail-proof product inventory.

4. Role of Dosimetry

Once the allowable dose limits D_{min}^{limit} and D_{max}^{limit} have been established by suitable studies, it is necessary to determine that these limits can be maintained in the process. For example, it may be required that they fall within legal dose limits set by a regulatory body, D_{min}^{legal} and D_{max}^{legal}. The degree of difficulty in controlling these limiting values of absorbed dose in the product depends on both the versatility of the irradiator and the physical properties of the items to be irradiated.

A simple case can be illustrated by a batch irradiator designed for the radiation processing of bulk liquids. In such an arrangement, the source and target geometry and the energy absorption properties of the target materials can be estimated beforehand easily. Accordingly, predictions of the dose limits are straightforward. These predictions can be verified in a series of irradiations, either by carefully planned dosimetry or by measuring the degree of radiation-induced change in samples of the product. The latter, however, is generally less reproducible and more costly than routine dosimetry.

A more complex situation can be illustrated by a continuous-process radionuclide irradiator, when it is used to irradiate a variety of nonhomogeneous materials. Under these circumstances, the flow of items through the irradiator creates a constantly changing irradiation condition at every point within the array of items around the source. This situation increases the difficulty of contriving a model from which expected dose limits might be predicted.

It is helpful to make preliminary estimates of the expected limits of minimum and maximum dose by considering extreme item loading situations, that is, those in which the conveyor source-pass positions are occupied by items which absorbed the greatest and the least amounts of radiation energy. Such estimates can be simplified further if it is assumed that the microscopic nonhomogeneity of certain items is not important. Experience has shown that such estimates of the greatest extremes of dose in a given item are usually overestimates; that is, measurements of the uniformity ratio, U, result in values of dose limits well within specifications. One reason for this is that at the surface of an irradiated medium the dose gradients estimated on the basis of monoenergetic monodirectional beams of radiation are generally less severe in practical circumstances. In practice, the energy spectrum is degraded and broadened and the beam is diffused somewhat by scattering processes.

The importance of applied dosimetry is demonstrated then through the dose measurements made during commissioning. Only after these measurements are made can processing be started with confidence and dose measurements continued to be used for maintaining quality assurance.

The upper and lower limits of dose to the food product for a given process depend on two factors: (1) the dose gradients within a given item (i.e., variability of dose throughout the food in its container) and (2) dose extremes among different items in a process run (i.e., variability of dose from the extremes of a low-density item in a series of low density items to the opposite extreme). The extremes of doses within a given item depend largely on the irradiation geometry, i.e., the configuration of the radiation field, and the size, shape, and density of the product. To a lesser but still significant extent, they also depend on the degree of homogeneity of material that is situated between and around each item as attenuators and scatterers of radiation.

Evaluation of the dose extremes within items is generally less complicated for most batch processes than for continuous processes. Nevertheless, this evaluation does depend on the overall irradiation geometry and on the composition of the food product, its container, and surroundings.

In continuous-process radionuclide irradiators, the situation is more complicated because of greater perturbations in the effective attenuation and scattering as the product moves through the irradiator. Consider the example of a large industrial irradiator that utilizes a shuffle-and-dwell multiple-pass irradiation scheme. In this type of irradiator, the source is generally surrounded by an array of several items similar in height, width, and depth.[3,133] Individual items proceed through the irradiator with each item occupying each dwell position for the same time period. The dwell time is determined by commissioning dosimetry, which ascertains the integral of the unique fractions of the dose at all dwell positions. The dose fraction for each dwell position varies from position to position due to the intrinsic nonuniformity of the radiation field and due to the ever-present attenuation by the product array. This shielding pattern changes somewhat as the bulk density of the items changes; consequently, with the exception of absolutely uniform and homogeneous product loading, it is not possible to predict precisely the effect of the shielding on dose levels and dose extremes within a given item. Here again a model is difficult to define because of the complexity of the large number of unique dose fractions comprising the total dose to the product.

It should be emphasized that a one-time determination of D_{min} and D_{max} for a given process should not bias subsequent locations or levels of these values for other processes. Estimates of locations can best be made by means of careful measurements of the dose distribution within typical items. It may be necessary at first to make rather detailed measurements of the dose distribution throughout a food item in its container, as the positions of D_{min} and D_{max} are apt to vary due to the variability of the dose fraction for each irradiation position on the conveyer and because of attenuation by intervening food items. Moreover, these factors can cause changes in the radiation spectrum at various locations in a given item, because of scattering, buildup, and attenuation at different depths of penetration. It is important, therefore, not only to keep track of the locations of D_{min} and D_{max} for each process, but also to measure the absolute values of these extremes and be aware that both the position and extreme values may change with new arrangements of food items. For example, making dosimetry checks of expected values of D_{min} and D_{max} always at the same positions in a product having a different bulk density or loading pattern in the irradiator may give erroneous readings of D_{min} and D_{max}.

It has also been observed that in continuous-process radionuclide irradiators, there is variability in the dose extremes within a given item as well as from item to item. It might, in fact, be misleading to specify absolute final values of D_{min} and the uniformity ratio for such a continuous process.

In good dosimetry practice, by making dose measurements in a series of irradiated food items, a series of dose extremes can be found. In the design of the process an important step to minimize variability of D_{min}, D_{max}, and U is to control certain geometric variables of the irradiation and prevent wide variations of bulk density. Another step is to assure that the operating process parameters are providing the prescribed values of dose through reasonable statistics based on correct dosimetry during commissioning. This permits the setting of confidence limits, that is, a range of values around the mean of each dose extreme:[3,7]

$$D_{min}^{limit} = \overline{D_{min}} - (ks)_{min}$$

$$D_{max}^{limit} = \overline{D_{max}} + (ks)_{max}$$

as illustrated in Figure 26.

Using a suitable sampling of dose values at the locations of D_{min} and D_{max} among identical items in a process, the standard deviations of N measurements of the dose extremes with a given dosimeter can be determined. By subtracting or adding the product of the standard deviation, s_{min} or s_{max}, and the tolerance factor for the measured values of D_{min} and D_{max} at a given probability level (as determined from appropriate statistics tables), k_{min} or k_{max} respectively, one can represent the limits of $D_{max} - D_{min}$ or $U = D_{max}/D_{min}$ according to technological experience with food irradiation and ascertain the confidence probability of these values meeting legal regulations. In an ideal case (see Vas et al.[7]):

$$D_{min}^{legal} = D_{min}^{limit} = \overline{D_{min}} - k_{min}s_{min}$$

$$D_{max}^{legal} = D_{max}^{limit} = \overline{D_{max}} + k_{max}s_{max}$$

but in most cases D_{min}^{legal} would be set slightly higher than the technological minimum dose, D_{min}^{tech}, whereas D_{max}^{legal} might be set either less than, equal to, or greater than the technological maximum dose, D_{max}^{tech}. It is necessary, of course, to have specified a probability level, P, and a sufficient sampling population, N, of dose measurements at the location of D_{min} and D_{max} in food items undergoing a given radiation process.

In considering specifications of dose limits, it should be pointed out that where the health of the consumer is concerned, as in radiation sterilization or pasteurization of foodstuffs, it is more important to adhere strictly to these procedures for staying within

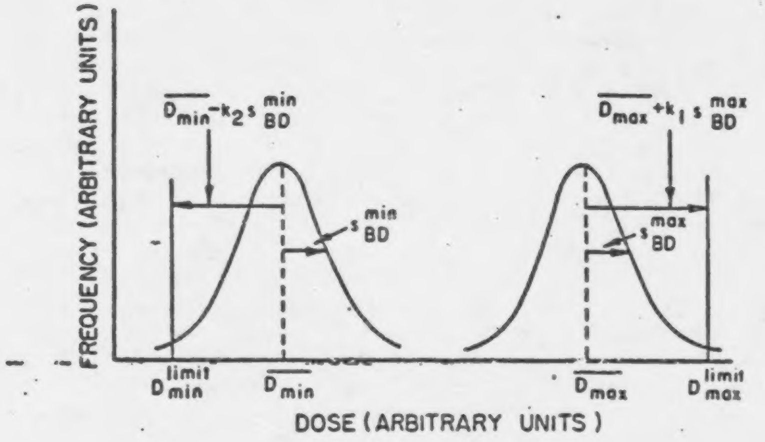

FIGURE 26. Frequency distribution of measured values of D_{min} and D_{max} in a series of packages of given geometry during radiation process run, with the sample standard deviations (s_{BD}) due to bulk-density variations and the confidence limits $k_2 s_{BD}^{min}$ and $k_1 s_{BD}^{max}$) indicated for a given number of random measurements. k_1 and k_2 are appropriate tolerances factors obtained from statistical tables for a given probability, P, and sampling number N.[3,6,7] (From International Atomic Energy Agency, Tech. Rep. Ser. 178, 70. With permission.)

authorized dose limits by means of accurate and precise dosimetry and by correct statistical application of dosimetry results.[3,7,234,238] With delayed sprouting and delayed ripening by irradiation, on the other hand, these factors are less important. In the more stringent cases, of course, the accuracy and precision limits of the dose measurements are vital. Therefore, not only are specifications of limits of dose to the food product to be made, but also limits of measurement uncertainties must be specified.

*5. Sampling**

In most radiation processes, it is impractical and unnecessary to place dosimeters in every item. The mean dose values, their standard deviations, and statistical uncertainties or probabilities can be determined by a sampling procedure. Such sampling is simply a scheme to gain information about the distribution of the variables of interest, in this case, the dose minimum and maximum in a given food item.

Among a group of items, the variable of interest is either the dose uniformity ratio, U, or the difference of the dose extremes, $D_{max} - D_{min}$. Estimates of these variables are derived from statistical information about the distribution of dose within a given item. Indeed, the necessary sample size N and the sampling scheme that are used depend to a large degree on how much is known about the distribution being sampled. It is helpful to have prior information about the relationship between the dose profiles within individual items and the locations of D_{min} and D_{max}. To a great extent, this information can be derived from process irradiation experience,[3,6] or it can be determined by making detailed measurements of energy deposition profiles in food-equivalent materials (i.e., a "dummy" food item) loaded with the production run at the same bulk density as the product. This knowledge then allows construction of a sampling scheme that is more efficient than random sampling. The latter is required only if no information about the distribution is available. The efficiency of sampling depends on the amount of information about the distribution that can be obtained from a sample of size N.

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* Dosimetry sampling during production would be difficult under certain process conditions, as when the foods are irradiated under refrigeration. Particularly in these cases it would be necessary to use preproduction dosimetry and production control would have to be based on parameter controls, e.g., time, weight, source and product position, and not on in-process dose measurement.

In considering dose distributions within a given irradiated item, an approximation of the profile can be considered first.[3,10,43,84,88,229,230] In addition, it can be assumed that measurements of dose at precisely positioned locations in an item provides more information about the spatial distribution of deposited energy than does the same number of measurements at randomly selected loctions. Furthermore, since it is known that within this sampling space the distribution of dose can in most cases be described by a well-behaved function exhibiting no discontinuities, it is possible to apply even more sophisticated sampling designs, such as central composite designs, which yield greater mapping detail with the same value of N.[234] By applying regression techniques to the measurements one may estimate the functional relationship between dose and locations within an irradiated item. Regions of extreme dose values can thus be identified using response surface methodology.[234]

After it has been shown to what extent absorbed dose varies with position within an irradiated item and how this distribution is affected by dwell time or conveyor speed,[3] it is important during commissioning to demonstrate that over a given irradiation time the total dose values have been controlled within specified limits, $D_{min}^{\text{"limit"}} = \overline{D_{min}} - (ks)_{min}$ and $D_{max}^{\text{"limit"}} = \overline{D_{max}} + (ks)_{max}$. Consequently, it is also important to analyze the variation of the dose extremes or uniformity ratios as a function of critical process parameters, such as dwell time, conveyor speed, mean bulk density, etc.

Such an analysis can be approached from several directions. One approach would be to treat accumulated dose as a variable which builds up at different rates and varies with location within a given item. By using this approach it is possible to apply a factorial in order to analyze the interaction between the factors, dwell time (or conveyor speed or residence time) vs. location within items.

Another simple experiment would be to determine in a typical food item $D_{min}^{\text{"limit"}}$ and $D_{max}^{\text{"limit"}}$ as a function of critical process parameters. It is possible to do this since we have general knowledge of conditions producing these expected values.[3,4,20,81] The purpose of this experiment then would be to measure the variable (absorbed dose) under the specific process conditions of interest.

In the case of continuous-process radionuclide irradiators, particularly the shuffle-and-dwell type,[233] desired process conditions can be simulated if the expected range of items (e.g., bulk density) to be irradiated is well-defined. The simulation would consist of four experiments:

1. Measure dose distributions in items of lowest bulk density by selective location of dosimeters in an item uniformly loaded to that bulk density and passed through the irradiator with products of interest having low bulk density.
2. Measure dose distribution in items of highest bulk density by selective location of dosimeters in an item uniformly loaded to that bulk density and passed through the irradiator with products of interest having high bulk density.
3. Repeat (1.), but pass through the irradiator with products having high bulk density.
4. Repeat (2.) but pass through the irradiator with products having low bulk density.

These four experiments provide an estimate of the expected dose extremes within an assortment of items of interest. Such experiments and their results are limited, however, since the data are valid only if the practical irradiation process parameters remain within the extremes used to perform these dosimetry experiments.

Special caution must be taken when one anticipates large discontinuous fluctuations in the energy absorption characteristics of inflowing items in a process run. This is particularly true if the fluctuations are due to large quantities of material of widely different energy absorption properties, i.e., abutting items of widely differing bulk densities or heterogeneities. Such conditions would exist in certain service irradiations for different customers in a single process run, where the processor is obliged to treat an assortment of items as they appear on the docket. Even in certain continuous or batch irradiators dedicated mainly to processing a single item batch or a small range of items, one may encounter discontinuities or random fluctuations in bulk density from item to item. These fluctuations may occur particularly when large quantities of items from the two extremes of bulk densities must be processed sequentially.

Frequently, these conditions warrant an adjustment in the dwell time or conveyer speed, so that the total residence time in the irradiator provides the desired value of D_{min}^{item}. When the processor anticipates this type of heterogeneous operation, it is helpful to know approximately how the dose extremes will fluctuate through the transitions. With a tabulation or chart of this relationship, the point or points at which dwell time or conveyer speed has to be changed can be determined. The prescribed lower limiting dose to the product (D_{min}^{item}) can thus be maintained within allowable uncertainty at all stages of the process.

Figure 27 illustrates typical transitions in dose achieved by adjusting irradiation parameters, either in a one- or two-step adjustment, in order to maintain relatively constant dose extremes in the product. Particularly in the situation where irradiation parameters must be shifted during the process, it is important to determine the dose extremes in the item through the transitions. This can be achieved from knowledge provided by the four experiments described previously; then by measuring the dose at one key position for a given sequence of items in the irradiator, each dose distribution result can be used to relate that dose to dose in another location. This key dose value can thus be related to a whole range of ratios of dose values throughout an item, once a general dose mapping has been established in a typical item.

All this information can therefore be used to estimate the expected dose extremes within items, by correlation with a single measurement of dose in some arbitrary location in one item of interest. Accordingly, data for the determination of the dose extremes through a process transition (see Figure 27) can be documented by placing dosimeters in a reference location in a random selection of items. In the case of discontinuities, this dosimeter location must be duplicated in a sufficient number of sequential items across dose discontinuities with time and should be extended for some distance or for several consecutive items into the constant dose plateaus, as shown in Figure 27.

D. Quality Control by Measurement Assurance

Once commissioning is complete and processing begins, dosimetry also plays an important role in maintaining quality control.[4] It may not always satisfy regulatory bodies to keep track only of process parameters set by dosimetry during processing. Jamming of the product on the conveyer or anomalies in the radiation field in the case of machine irradiators may cause unexpected down time in the process. A dosimeter sampling scheme or placement of suitably calibrated routine dosimeters at a strategic location in or on food items may frequently be needed for quality assurance.

The frequency of use of these dosimetry checks of the process is determined by the recommendations on food irradiation, such as those supplied by the Codex Alimentar-

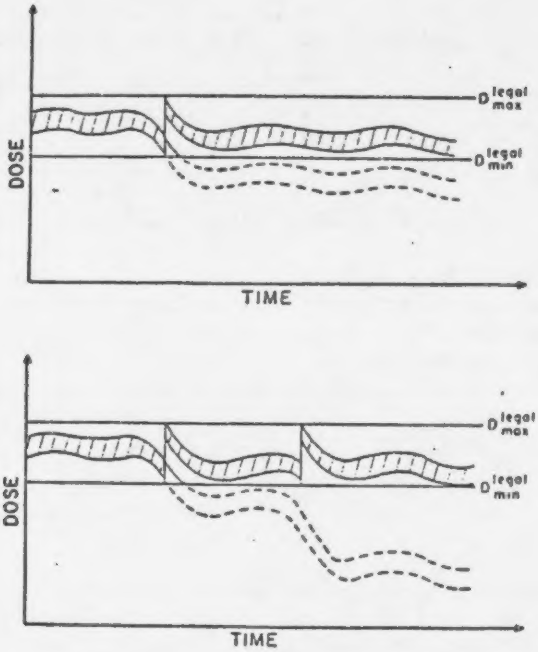

FIGURE 27. Variation of total dose limits in a food product with time (shaded area) as various items progress through an irradiator. One- or two-step transitions are made in irradiation parameters (i.e., dwell time or conveyor speed) to compensate for measured dose limits straying outside legal limits of D_{max} and D_{min}, due to product changes, such as bulk density changes, or self-shielding changes with position on the conveyor.

ius Commission of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). In a cobalt-60 gamma-ray irradiator that processes nearly always the same product, reliance on irradiation parameters and only occasional dosimetry checks (say once a day) may be sufficient. On the other hand, when there are many discontinuities, heterogeneities, and anomalies of irradiation geometry and food items in either a continuous or batch process, dosimetry checks may be required in every item.* The processor must, at any rate, have immediate access to reliable routine dosimetry and knowledge of detailed dose distributions in all products of interest. He can then place the dosimeters in predetermined locations and ascertain by means of measurement assurance that the process is meeting specifications. All possible sources of error and uncertainty in dose interpretations by the dosimeter must also be monitored, with suitable corrections being made. Typical dosimetry parameters to be reckoned with for achieving *Measurement Assurance* are:

1. Dosimeter response function or calibration curve shape
2. Calibration precision limits at various dose levels
3. Temperature dependence of dose interpretations, both during and after irradiation

* Because of the cost of using large numbers of dosimeters, the processor would need to evaluate the expense of permitting variation of product bulk density against the expense of the dosimetry.

4. Other environmental factors (e.g., humidity, light, atmosphere)
5. The effects of variations in absorbed dose rate or dose fractionation on the response
6. Dosimeter stability factors before and after irradiation
7. Variations within a dosimeter batch or between batches
8. The effect of dosimeter size
9. Radiation scattering effects on the response of dosimeters placed near interfaces (e.g., dosimeter wall effect or need for cavity-theory corrections)
10. Effect of differences in radiation spectra between calibration and application or during use (e.g., need for a dosimeter that matches the food product in terms of radiation absorption properties)
11. Effects of adverse handling (e.g., scratches, finger prints) on reliability of dose interpretations
12. Effects of imprecision and error in specific optical absorptivity or other dosimeter signal factors on dosimeter reproducibility and accuracy

VII. CONCLUSION

In planning correct dosimetry for radiation processing, it is important to set up suitable procedural *guidelines* and *checklists* and to follow dosimeter *selection criteria* tailored for a given radiation process.[3]

The radiation facility operator must be capable of good dosimetry practice and documentation of dependable dosimetry data, in order to satisfy regulatory guidelines. A typical set of *guidelines* for this purpose is as follows:

1. Demonstrating capability of measuring accurately the absorbed dose in a reference material (e.g., water or plastic) with a routine dosimeter
2. Representing in a meaningful way the dose interpretations by means of appropriate calibration procedures and corrections for systematic errors
3. Converting the dose as interpreted by a reproducible routine dosimeter to dose in the food product or equivalent substance
4. Deriving useful information about the dose distribution in the product
5. Adjusting process parameters to meet specified values of minimum dose and uniformity ratio
6. Maintaining ready access to proper calibration of routine dosimeters
7. Keeping acceptable dosimetry records, including statistical data, at all stages of research, commissioning, and processing

In the choice of routine dosimeters for process applications in a plant, the following are suggested *selection criteria*. The dosimeter should have:

1. Capability of reliable calibration and standardization
2. Adequate reproducibility at all specified dose levels
3. Limited dependence of response on radiation spectra and absorbed dose rates used in the process
4. Approximate product-equivalence in terms of radiation absorption properties
5. Correction factors for various systematic errors, such as humidity, temperature or light effects, instabilities, and readout imprecision
6. A fixed size and shape for solving the dosimetry problem at hand
7. Low cost, ruggedness, simple handling, and ease of read-out procedures
8. Ready commercial availability in reproducible lots and batches with long preirradiation shelf life

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NBS SPECIAL PUBLICATION 250-MAY 1984
APPENDIX
FEES FOR SERVICES

CALIBRATION
AND
RELATED MEASUREMENT
SERVICES

This appendix is issued in April and October of each year. If you do not have the latest issue, write or call:

Office of Physical Measurement Services
National Bureau of Standards,
Physics Building Room B362
Washington, DC 20234
(301) 921-2805.

OF THE NATIONAL BUREAU OF STANDARDS
U.S. DEPARTMENT OF COMMERCE

ORDERING INFORMATION[†]

GENERAL

The Headquarters of the National Bureau of Standards is located in Gaithersburg, Maryland. In addition NBS maintains a major facility at Boulder, Colorado. Certain calibrations are performed in Gaithersburg while others are performed in Boulder. Accordingly, it is necessary to determine at which location the desired calibrations are available, so that your instrument or device and purchase order can be shipped to the proper location. Services beginning with the numbers 4 through 6 inclusive are performed in Boulder. Specific instructions on where items are to be shipped and points of contact for each technical area are given in this Appendix.

REQUEST PROCEDURE

A formal purchase order for the calibration or test should be sent before or at the time the instrument or standard is shipped. This should provide:

1. clear identification of the device being submitted (make, model, serial number, description);
2. the test procedure to be followed; e.g., 1.1B (or other procedure if not the normal NBS procedure);
3. the name and telephone number of the person in your organization responsible for this procurement;
4. the name and telephone number of a technical point of contact familiar with this request and;
5. separate instructions for return shipment including the matter of insurance (for details please see SP 250, Chapter I Section D), mailing of report and billing.

Acceptance by NBS of purchase orders does not imply acceptance of any provisions set forth in the order contrary to the policy, practice, or regulations of the National Bureau of Standards or the U.S. Government. Orders from outside the U.S. require special arrangements, contact the Office of Physical Measurement Services for details.

[†] Chapter I of NBS Special Publication 250 provides more detailed information on these procedures.

8.6 DOSIMETRY FOR HIGH-DOSE APPLICATIONS

Direct inquiries and shipments to the attention of: W. McLaughlin or J. Humphreys, Radiation Physics Division, RAD PHY--C216. Telephone: 301-921-2201.

At Cost	8.6A§	Special measurement services
$. 112	8.6B§	Irradiation with ^{60}Co gamma rays of customer-supplied dosimeters or samples (up to five at each dose) to a specified absorbed dose in the range 10 to 10^6 grays (10^3 to 10^8 rads)
136	8.6C§	Provide dose interpretation of NBS-packaged dosimeters irradiated by service customer (each dose point)
11	8.6D§	Spectrophotometric reading of dosimeters, optical density at one to five wavelengths (each dosimeter)
46	8.6E§	Spectrophotometric reading of dosimeters, ultra-violet and visible spectrum scan (each dosimeter)

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§ Special Test Only

IMPORTANT NOTICE

Inquiry and Shipping Addresses
Gaithersburg Services

Postal Service Inquiries and Shipments

ATTN: J. C. Humphreys
Building 245, Room C216
National Bureau of Standards
Gaithersburg, MD 20899

Shipments by Common Carrier

X-Ray Physics Group
Building 245, Room C216
National Bureau of Standards
Route 270 and Quince Orchard Rd.
Gaithersburg, MD 20899

PRICES

Firm prices or not-to-exceed prices (including "at cost" items) are only guaranteed in writing on the Acceptance copy of the NBS Form 64 sent to the customer or in writing from the Office of Physical Measurement Services. "At Cost" items are those services for which the price varies depending on the particular device submitted and the particular measurements requested. A phone estimate can normally be provided.

For detailed information on prices please refer to the points of contact listed in the Appendix or the Office of Physical Measurement Services at the address given on the front cover of the Appendix.

For non-Federal sponsors, the U.S. Treasury regulations require late charges based on the current value of funds to Treasury be assessed for each 30 day period or portion thereof that the payment is delayed. Therefore, each non-Federal contract or agreement should contain terms for payment as well as a provision for imposition of late charges.

TECHNICAL PAPER GPS 334

THIRD GAMMA PROCESSING SEMINAR

AECL

Consumer Acceptance of Irradiated Food

By

MARILYN YOUNG
CONSUMERS' ASSOCIATION OF CANADA

OTTAWA, ONTARIO
JUNE 6-9, 1983

Atomic Energy of Canada Limited

I have been invited to speak to audiences concerned with marketing irradiated food products 2 or 3 times before. On those occasions I have listed all the real and I must confess, assumed reactions of consumers to irradiation. Canadian consumers have not come face to face with these products since the potato fiasco in the early 60's. I have stressed the need to take consumers into your confidence. Explain the what and the why of this procedure. I have gone to great lengths to ask for a strict code of practice or protocol for food irradiation to be drawn up and agreed to internationally. I have asked for labelling of the products, primary, secondary or minor ingredient. So far there has been no agreement with my line of thought or requests from the regulatory bodies or from food processor or food irradiator. In light of this you'll agree I have some nerve coming before you now, without having changed my mind, but still hoping to change yours. To do so, I want to take this opportunity to tell you what has happened so far in Canada and how it came about.

The first time that I and other members of the Food Policy Committee of the Consumers' Association of Canada (CAC) - an organization with 175,000 members, heard anything about the new interest in food irradiation was 2 years ago. Mr. Fraser and Mr. Ouwerkerk came to our committee and spent an evening explaining and answering questions. They didn't find these questions outlandish or unreasonable and in the end that committee accepted gamma processing. They not only accepted it but went further and urged all of the Consumers' Association to accept it and that they in turn go even further and recommend that the Government of Canada accept the General Standards. But I'm getting ahead of myself, because I wanted to explain that that first food committee represented consumers from all provinces, all seriously interested in what kind of food goes onto the Canadian table. They don't represent the far out group that is 'agin anything and everything that is done to food to change its pristine dirty and infected state'. So in that respect perhaps they were an easy audience, though I believe there are some "anti-nucs" among us. They do however represent a group that does look very critically at each proposal, investigate things thoroughly before passing judgment. This is the committee to whom the Canadian Department of Health and Welfare and the Canadian Department of Consumer and

Corportate Affairs appeals for reactions before instituting changes in food handling processes or labelling. It didn't take very long to convince this group that gamma processing could indeed be a valuable tool for the food industry, and a benefit to consumers world wide. They next questioned why we weren't already reaping the benefits in Canada. Here we found a chicken and egg situation where industry hadn't gone ahead because regulations wouldn't permit it, and regulatory agencies weren't moving because industry hadn't asked them to and both were wondering how the consumer would react.

Somehow it fell on me to find and represent the latter. I drew up a resolution for the consumers to vote on at their annual convention. Now you must remember that this was a new, unexplained idea to hit the delegates just prior to the convention. Because most delegates had never heard of processing food with ionizing energy, as we were calling it then, we asked A.E.C.L. to be on hand one afternoon to set up a display and answer questions. Frank and Theo came and gave their slick picture show and explained and answered questions all one afternoon to any who could slip away from the other sessions to learn about irradiation. I took the hot seat for an hour so that 250 delegates could ask many more searching questions. When the time came the delegates representing 175,000 members voted in favour of 2 out of 3 of the resolutions on food irradiation. The resolutions are included but for brevity I'll just explain that after a lot of 'Whereas Clauses' to explain the resolution when it came down to a request that C.A.C. accept and support the Codex International General Standard for Irradiated Food and the recommended Code of Practice for the operation of Radiation Facilities and that the Government of Canada be asked to do likewise, but, in addition, in order to inform the consumers of the method of presentation used, require all foods processed with ionizing energy be so designated in a clearly recognizable manner. The 2nd resolution asked the Departments of Consumer and Corporate Affairs and Health and Welfare Canada to develop an appropriate symbol to identify any food which has been gamma processed, and to promote such a symbol internationally. It was further resolved that this symbol be required to be in close proximity to the name of the irradiated food and be displayed on all informative material at point of sale on all bulk food so treated. The 3rd resolution went further to suggest that the symbol used should be green in colour -- a known 'go ahead colour' implying neither warning or danger.

They did not accept the 3rd resolution because to do so would imply endorsement or promotion in the eyes of some, unnecessary cost in the eyes of many others. The role of C.A.C. is to react to procedures in the market place to ensure that the consumer is protected. But the main point of that story is to point out that by stealing a few minutes here and there with the delegates during a very busy 3 day convention, the majority of the consumers, not all mind you, were willing to have the food processed with ionizing energy. The Department of Health and the Department of Agriculture have acknowledged our requests and have instituted programs to act upon them.

Since the C.A.C. convention, the Canadian press and T.V. have become interested in our resolution and why it was passed. Ruth Titheridge, our Food Committee Chairman, Chris Bisanz at the National Office and I have spent many hours on the phone talking to reporters and T.V. producers. Usually it is necessary to start from the very beginning, telling them what gamma processing is, what it is used for and on what; why we want it, etc. After explaining as well as we can we refer them to A.E.C.L. for expert information and data. I've been keeping a press file and so far there has not been one negative article written and surprisingly little adverse reaction from the public to these articles. So why you may well ask, have I been telling audiences that the 1st reaction to food irradiation is horror, revulsion, disbelief that we could seriously anticipate such a thing. In fact that is what the reaction usually was. Not until my friends, colleagues, media, etc. heard an explanation and an assurance did they accept it. These are normal reactions and fears of the unknown, particularly when it is associated in any way with the nuclear industry. That is why I have been saying and continue to say "a consumer education program is essential". This education program should not be left to the Consumers' Association of Canada. You who are in the business or plan to be in the business of food irradiation should be starting your campaign now. I think it is called a "softening up" process and believe me, there is a lot of stiff resistance. I feel strongly about this education program, particularly since I have been told over and over again that food irradiation is no longer a technical problem but a psychological one. That being the case, it is time to hire the ad men and marketing men so that they can be taught the facts that they are to convey to the consumers. I did say a softening program not soft soaping. Everyone takes anything to do with the nuclear industry seriously and so only hard facts on which to base assurance will be listened to. The public probably will not react strongly to articles you might feed to the press or media. At this stage in their minds it is all purely theoretical. When the food is on the grocery store shelf, that is when you will see how well they accept your explanations and assurances. This is when the letters to the editors will fly; but more importantly, when the choice will be made -- to buy or not to buy. I have been assuring you that they will buy if you present them with the facts and let them make that choice.

But "Choice" I insist is the right of the consumer. No matter how reassuring you are, not everyone is going to be convinced. I'm not talking about the so called "emotional kooks" who won't believe anything. The people I have in mind are an educated segment of the population who are at this point expressing grave doubts and concerns and are saying they do not intend eating irradiated food. There is a doctor in Manitoba who is saying "the food is not going to receive a harmful dose of irradiation but during the process, the packaging will give off damaging hydro carbons and contaminate the food". Another scientist in Toronto says he wouldn't touch it -- "the irradiation may kill most of the micro organisms but what about mutations among those that are left". I have given such people answers, you can give such people answers, and you should but the final choice should be theirs.

During a marketing conference in Vienna we had long discussions about this point and I admit that I was in the minority in pushing for labelling. I was among processors and marketers who of course would find life much simpler if no label was required. It would be much easier to sell the benefits and not mention the process. Long lasting strawberries sure sounds better than irradiated strawberries. Of course, I haven't asked you to call them irradiated strawberries or treated with ionizing energy strawberries. I've asked you to use the international symbol. I don't want a label that will necessarily alert or alarm. Nor is the label the place for education. A label is to give specific information. The information we want conveyed is that this food has been irradiated; but we don't want to use that term. We agree that is misleading. It leads the average person to believe the food could be radioactive. However, we do want to inform those who, for whatever reason, choose to avoid the gamma processed food, just as we want to inform those who are looking for it and want to buy gamma processed food. By using a recognized symbol, both groups would be satisfied without unduly alarming those who have no strong feelings one way or the other. To illustrate my point I use the analogy of the pure wool symbol which we all recognize and is known world wide. If I had an allergy to wool, I'd look for the symbol when buying a suit so that I could avoid it. So too, I would look for the irradiated symbol if I didn't want to purchase that product. If it didn't matter to me whether the suit was made of wool or synthetic, I might or might not notice the symbol even though it was there. This could well be the case with most food shoppers. If on the other hand I thought wool was the best wearing suit and what I wanted, I'd be looking for the symbol. So too, when I'm stocking up on potatoes in the fall, I'm going to look for that symbol. When I'm shopping on Friday for special company coming for dinner on Sunday I'm going to look for that symbol on the chicken and strawberries. Besides, how can Mrs. Fraser know which are the clean, safe spices if they aren't marked and Frank doesn't want anything but irradiated spices in the house.

Getting back to the discussion of labelling irradiated foods that took place in Vienna. That group listed the main reasons for not labelling as follows:

- Irradiation is a physical process and it is not required to state it on the package (label);

- Misleading words or statements must not be made on the label;

- Labelling is not a vehicle for education;

- Limited space on the label precludes adequate information and description of the process;

- Industry may use labelling to over promote quality (improvements);

- Because of the objections in some countries, it will prevent maximization of the process and its benefits.

Then we listed the reasons for labelling which were:

- Informs consumer, prevents suspicion and accusation of lack of integrity and honesty;
- Consumers have a right to be informed and choose;
- Potential (of) preference because of the labelling;
- Forces industry and others concerned to promote educational programme.

I don't know how quick you were to count, but I'll admit that more reasons were given for not labelling. At this point in the conference, when the consensus about 15 to 1 was for recommending that irradiated foods not be labelled as such; the chairman turned to me, hoping to make it unanimous and said, "Well Marilyn, can you live with that?" My reply was "Yes, I could live with it if certain other requirements were fulfilled." Which I'll enlarge on later but the more serious question is "Can industry live with that recommendation?" Here I have grave doubts. I truly believe that attempting to market irradiated foods without telling the consumer would backfire. It is too emotional a subject. It certainly can't be carried out like some clandestine operation. Too many people are involved. There will be the movement of radioactive material into food plants, etc. When the news leaks out, as it certainly will, then the wild rumours will fly. The ecology groups will be up in arms, the "don't poison our food groups" will parade, the headlines in the newspapers will be wild. Then you will be faced with not just a straight forward education job but the job of putting down rumours as well. A negative image is much harder to deal with.

Of course we all know that lots of processes do not appear on labels, but that isn't necessarily right. We are all familiar with the argument that the irradiation process has been proven safe, it adds nothing so there is nothing to label. The consumer, however, doesn't want any more decisions made by some unknown group. Such decisions were made for us before and then later admissions had to be made that perhaps these hadn't been the right decisions. Perhaps the foods were not all that safe. Some examples that come to mind are saccharin as a sweetener, nitrates in meat, ethylene oxide to disinfect foods, chemical decaffeination of coffee, to mention a few. The first two are definite additives, the second two were processes that were at first reputed to add nothing and to be safe. The consumer has a right to be suspicious and want to make up his own mind. I realize in all likelihood it will be an emotional rather than an informed decision; but if you and your marketing experts inform and assure the public, well I'm sure the selling will be easy. The important thing in marketing, of course, is to explain and sell the benefits, then add the symbol to the label so we can recognize the improved products.

Perhaps now I'd better be more specific about what I want labelled, because here too I know I'm in for an argument. The consumer really wants full labelling; that is the primary product -- lets say wheat, the secondary products - that would be flour, and the third stage that is the bread - at least the flour in the ingredient list on the bread not the loaf. You and I know the argument that cooking or further processing changes the state of the ingredients far more than the irradiation did, but the consumers don't and may not believe you when you tell them. They want the right to avoid or choose those products. Adding the irradiation symbol in the same size type as used in the rest of the ingredient label is not going to cost more, nor take up much more space even on a multilingual label. Some countries are frowning on the use of symbol in general, preferring to use a name such as processed by ionizing energy or gamma processed on the display panel of irradiated foods and single ingredient foods but ignoring the list of ingredients altogether. This first part we could agree to, but feel that the symbol would be very appropriate in the list of ingredients which have been irradiated. Some of you are no doubt tired of hearing about my can of chicken stew, but I'll use it again to illustrate my point. A consumer may purchase a can of chicken stew. Nowhere on the label will they find the word irradiated or the symbol because it wasn't irradiated. It was probably pressure cooked or some such other process. However, it is quite conceivable that it contains irradiated chicken, irradiated potatoes, irradiated flour, irradiated carrots, irradiated onions, irradiated spices. Now if this consumer has vowed never to eat or serve her family irradiated food how can she choose or avoid them, if it isn't labelled.

If this canning company changes its process and switches to irradiating some sort of pouch package, then the consumer is faced with the dilemma of double irradiation but still no way of knowing it. I think what it boils down to, is that if you have to put it on the label then you will have to explain it and we avoid that old fashioned unacceptable attitude of "Father knows best what's good for you". When I speak of labelling I mean more than most of you. I'm referring not only to prepackaged commodities but I also want to see that symbol at the point of sale on bulk foods too. If we don't carry it all the way, then the skeptical consumer is going to switch from buying prepackaged goods to buying from bulk bins or in so called "Health Food Stores", assuming as they so often do now with chemical additives, that because it isn't labelled it isn't there. Most irradiated potatoes, onions or soft fruit are sold either in bulk or prepackaged. To prevent unfair competition both should make a declaration. Food irradiation is going to be a worthwhile useful tool, by all means go ahead and sell its benefits, but don't be afraid to say how you got them. We like the idea of the sticker on commodities such as South Africa has been using and the same way that Dole and Chicita use logo stickers to identify their products.

The conditions I put on my agreeing with the members of the consultant meeting on marketing or irradiated foods to marketing without full labelling had to do with controls within the industry itself. If the consumer is not going to be able to choose, then we must do everything possible to make sure there is absolutely no reasons to even consider rejecting irradiation. The purpose of the process is to produce "Wholesome Food", which I take to mean safe and nutritious. We must have complete assurance that each and every batch of irradiated food meets international standards of wholesomeness. Consumers should feel confident that the food irradiated in Ti, Israel, or California will meet the same high standards. When I ask you to inform and assure the consumer, I want that assurance based on fact, not just on theory. Remember the market can be a very unforgiving place. One false move, one bad lot, one bad headline and you will have lost the consumers' confidence, and the industry will be in jeopardy. The pioneers in the food irradiation industry feel I'm pointing an accusing finger at them when I insist on tighter controls and more policing of this process than other food processes. This isn't the case. I have every confidence in what has been done to date -- you didn't see me hesitate to eat any of the irradiated foods at the irradiated food reception given by I.A.E.A. I am, however, concerned about what can happen when the industry expands beyond the friendly brotherly group now involved. Big industry is going to take over this process and if they can cut corners to save money or make money, they might be tempted to. So really what I'm aiming at is insurance for the food processing industry itself when I ask for a strict written code of practice or protocol, and an inspection system which must be agreed to and adhered to in order to get and keep a licence to irradiate food. Those of you who have been involved in medical supply irradiation know what I'm talking about -- a code which spells out not only G.M.P. but also the allowable bio-burden pre-irradiation, the quality of food that can be irradiated; regulations regarding the number of perspex dosimeters per box, their distribution per load and even a requirement that each load be routinely monitored. Have you yet agreed on standardized dosimeters or lists of dosimeters which can be compared to callibrated graphs or charts. Without standarization the information on a shipping document after irradiation is meaningless. The consumers would like to see irradiation facilities licenced and inspected once a year at least by representatives of some such authority as the standards for weights and measures or its equivalent in each country which would ensure that the standard emissions related with time and speed of the machine match a minimum standard curve. This would be a third tier of inspection over and above the product inspection and premise inspection that any food processor would expect.

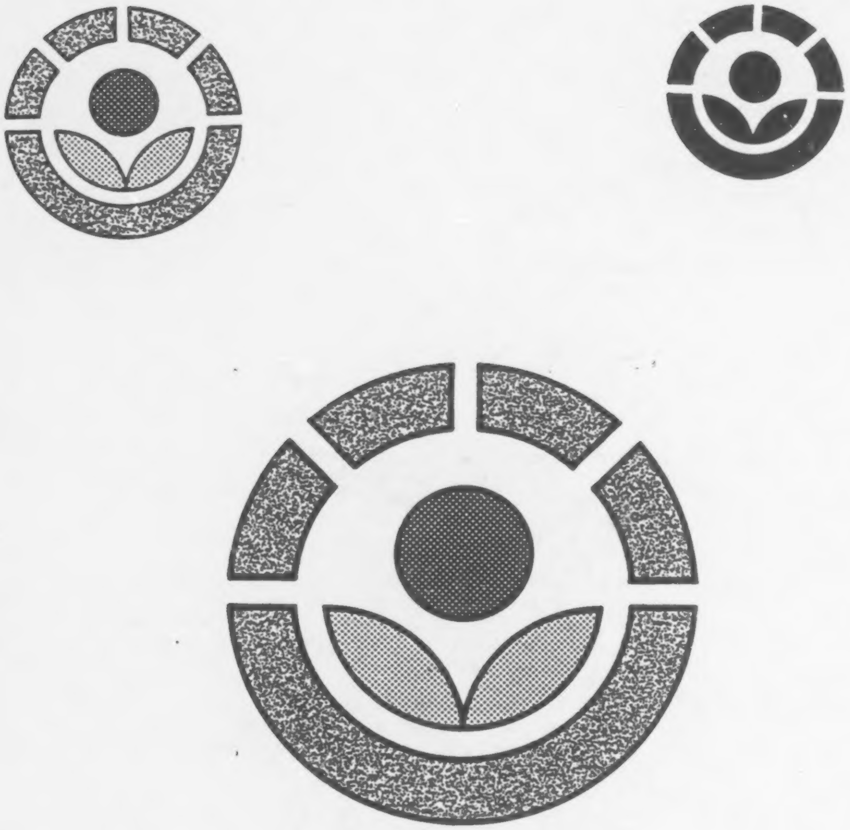
At the moment, consumers are accepting your assurances that irradiated food is wholesome, that is, it is safe and nutritious. Of course, food handling regulations in any food processing procedure are designed with this in mind. Hence the argument that the irradiation industry doesn't need special rules. My counter argument is that the special rules I'm asking for are not particularly difficult to adhere to, in fact, through gentleman's agreement, I think you are doing most of the things now. But after 20 years of research, thousands of dollars and millions of man hours spent on developing this process, let's not make it possible for someone to ruin the reputation of all.

Not only are consumers asking about the food -- is it safe? Does it still have its normal vitamin content? Is there an adverse accumulative problem? Are there any mutations formed? Does it taste and smell good? Is it radioactive? Is it toxic? Is it carcinogenic? How do you know it is safe, what happens if it gets too much irradiation, what about new compounds formed during the ionizing process -- what are they? Are they toxic? Mutagenic? etc. How much will it cost? And many more such questions; they are also very interested and concerned about the facilities. You no doubt are exasperated by the usual assumption that when you refer to an irradiation plant, that you are in fact talking about a type of nuclear reactor. We are all sick of the name "Three Mile Island", however, this is one very important area which shouldn't be ignored in your public education program. Try to think in layman terms and you'll realize that irradiation means radioactive, irradiator means reactor which means danger. We've also been answering questions about transport of hazardous products, radioactive waste, proliferation of reactors to make all the necessary cobalt 60, contaminated cooling water disposal, worker safety, to mention just a few.

Then there is the rather interesting question you may not have anticipated "Why do we need it? We have safe nutritious food now." Do you realize that only those people in the food industry know that spices, herbal teas and such like are infested with insects, eggs and larva as well as fungus and must be disinfected. Do you realize that most people never know that their citrus fruit might have been gased. Do you know that the majority of consumers don't know that fresh fish and poultry could be covered with disease causing organisms. They assume that government inspection assures them of salmonella-free food. In teaching the public about the benefits of food irradiation, naturally one doesn't want to alarm them about the state of the food they are eating now. They would be glad to hear though, that irradiation can reduce the number of chemicals used on food eliminating the fear of toxic residues of insecticides and fungicides. Most people have never considered that the packaging material around their food had been sterilized. I think it would be quite a revelation to most consumers if you told them how much irradiation is now a part of their lives, particularly in sterilizing packaging and medical supplies

--including those used internally. By stressing the positive, healthful benefits, irradiation of food would seem a logical outgrowth of such developments.

I feel very positive about processing food with ionizing energy and feel that the benefits are going to be welcomed by the public once they are told about it. That, however, is the tricky part. How do you explain it without using that much feared word irradiated. I've been advocating avoiding it by all means. The consultant meeting in Vienna recommended not labelling as I said, but added a rider that if government regulations made it necessary to label then "avoid any word full or partially containing words like radiation or ray". They went on to suggest the usual euphemisms - gammatized, ionized, processed by Pico Waves or with electrons or gamma treated, etc. The more involved I become the more I realize changing the name is nigh on impossible. I've used it repeatedly here among a sympathetic and understanding audience. Besides it was easier and I expect you all use it regularly. I can show you three newspaper articles that state in the body that Mrs. Young of the CAC would like to see the process referred to as processing by ionizing energy or the use of a symbol so as not to confuse the public with radiation. Each of these articles bears a headline containing the words "Food Irradiation" even though I had avoided the term like the plague. So maybe we will have to use it occasionally along with other preferred terms in the public education program; but I still feel that little International Symbol is what I'd like to look for on the grocery shelf.



FOOD IRRADIATION SYMBOL

1982 RESOLUTION

3. IONIZING ENERGY FOOD PROCESSING (a)

WHEREAS efforts to ensure a safe and adequate world food supply are made more difficult by the loss of up to 40% of the world's annual crop yield to micro-organisms and insect and parasite infestations, despite continuing massive use of chemical controls, and

WHEREAS processing by ionizing energy has been shown to be a technology capable of preserving food supplies by eliminating pathogenic and food spoilage micro-organisms, inhibiting sprouting in onions and root vegetables and by permitting greater hygienic safety to be maintained during food storage and processing, and

WHEREAS food processing by ionizing energy could reduce or eliminate the need for chemical preservations and permit a significant reduction in the amount of energy used in food processing, and

WHEREAS foods processed by ionizing energy have undergone extensive testing over the past 20 years to ensure that no toxic, mutagenic or carcinogenic factors are present after processing, and

WHEREAS these tests have been reviewed and confirmed by the Joint FAO/WHO/IAEA Expert Committee on the Wholesomeness Irradiated Food, and

WHEREAS internationally accepted levels for processing with ionizing energy and safe practices for this operation of radiation facilities used in the processing of food have been established under the Joint FAO/WHO Food Standards Program; therefore,

BE IT RESOLVED that CAC reaffirm its policy of support of use of ionizing energy processing for sprout inhibition of onions and potatoes as resolved in 1965 and extend this support to the provisions of the Codex Recommended International General Standard for Irradiated Food and the Codex Recommended Code of Practice for the Operation of Radiation Facilities.

BE IT FURTHER RESOLVED that the Government of Canada be asked to adopt the provisions of the Codex Recommended International General Standard for Irradiated Food and the Codex Recommended Code of Practice for the Operation of Radiation Facilities as Canadian regulations, and in order to inform consumers of the method of preservation used require all foods processed with ionizing energy be so designated in a clearly recognizable manner.

Adopted June 1982

FOOD

4. IONIZING ENERGY FOOD PROCESSING (b)

WHEREAS ionizing energy processing, sometimes referred to as food irradiation, is a physical process which adds nothing to the food but by its name can alarm the public and thus decrease consumer acceptance and processors' use; therefore,

BE IT RESOLVED that CAC request Consumer and Corporate Affairs Canada and Health and Welfare Canada, to cooperate in developing an appropriate symbol to identify any food which has been processed by ionizing energy or which contains as an ingredient a product so processed, and to promote the adoption of such a symbol internationally, through the General Standard for the Labelling of Prepackaged Food of the Joint FAO/WHO Food Standard program.

BE IT FURTHER RESOLVED that CAC request Consumer and Corporate Affairs Canada and Health and Welfare Canada to require that this symbol:

a) be in close proximity to the name of the irradiated food in the list of ingredients of a prepackaged food product; and

b) be displayed on price cards, posters or other informative material at point-of-sale of all bulk of unprocessed foods so treated; and

c) be required to accompany the name of the food in all mandatory documents accompanying shipments of non-retail containers of food as set out in the General Standard of the Joint FAO/WHO Food Standard Program.

Adopted June 1982

1982 PROPOSED RESOLUTION

FOOD

3(c). IONIZING ENERGY FOOD PROCESSING

WHEREAS the colour green has become established in consumers' minds as a "go ahead" colour implying neither warning nor danger, and

WHEREAS Consumer and Corporate Affairs Canada already has designed and implemented successful programs utilizing symbols and colour to convey information on fabric care and hazardous products to consumers; therefore,

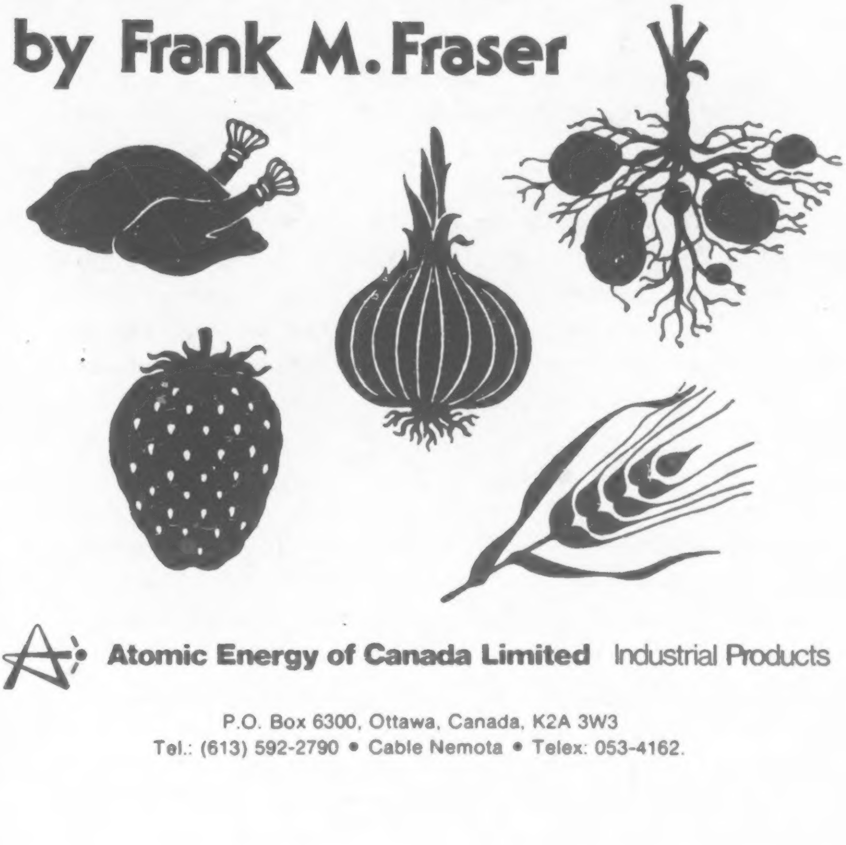
BE IT RESOLVED that CAC request Consumer and Corporate Affairs Canada to utilize the colour green for the symbol identifying (irradiated) ionized energy processed foods and to undertake an educational program to inform consumers of the significance of such symbols and colour as used on foods processed by ionizing energy.

**N.B.: This resolution was received after the deadline and is therefore subject to rewording, pending revision by the Resolutions Chairperson.

NOT ADOPTED

Historical Overview and Potential of FOOD IRRADIATION

by Frank M. Fraser



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HISTORICAL OVERVIEW
AND
POTENTIAL OF FOOD IRRADIATION

One of the greatest challenges facing the world today is the availability of sufficient food supplies to meet the needs of a rapidly growing population. The world population in 1980 was estimated at 4.5 billion and is expected to grow to 6.1 billion by the year 2000.

The majority of this population increase will occur in countries where food shortages already exist. The United Nations has estimated that some 50% of the world's population suffers from hunger or malnutrition.

The total technology available to mankind must be applied to solve this problem. Today, this problem is being tackled in two major areas, the first being the improvement in agricultural and farming techniques, the second, in which our expertise would apply, is the preservation of food wholesomeness as it moves from the farm to its point of final consumption.

Several such preservation techniques are in use, in fact some have been employed for hundreds of years, techniques such as drying, salting, freezing, to name a few. However, the development of radiation processing technology over the past 25 years has given mankind another tool for increasing the total food supplies.

The current availability of large sources of Cobalt and gamma irradiation processing equipment make possible the bulk or packaged treatment of foods. This technique may prove to be as revolutionary as the discovery of canning nearly 175 years ago! Combined with other modern methods, such as new packaging and transportation techniques, the use of food irradiation can make a major contribution to increasing the world's food supply.

Atomic Energy of Canada Limited has always been a leader in the development of irradiated technology and is one of several agencies world-wide that pioneered the use of gamma irradiation for food preservation. After more than 25 years of research the barriers to the commercial development of food irradiation are slowly, but methodically, being overcome.

Food irradiation promises to become a major world-wide industry, based on nuclear technology, in the next decade. However, before this can happen we must apprise the world of the availability of irradiation processing equipment and encourage the development of international legislative procedures endorsing its use.

Our experience in food irradiation dates back to 1956 when Ken MacQueen began investigating the effects of gamma irradiation on vegetables. He found that irradiation was a very potent sprout inhibitor and that a dose of 8,000 rads was very effective to control sprouting in the main commercial varieties of Canadian grown potatoes.

On November 9, 1960, as a result of research done in major universities across Canada using AECL built Gamma-cell 220's, the Canadian Government unconditionally cleared for human consumption the use of irradiation to inhibit sprouting of potatoes - a first in the Western World. This was followed by the unconditional approval for sprout inhibition of onions in March of 1965 and insect disinfestation in wheat, flour and whole wheat flour in 1969. In 1973 test marketing approval was received for the radiation processing of poultry for salmonella control, along with cod and haddock fillets to extend their shelf life.

Our food irradiator equipment technology began in

1961 with the design, manufacture and commissioning of the world's first mobile Cobalt-60 irradiator. It was built after the food and drug clearance for irradiated potatoes had been obtained. Its main purpose in the first season of operation was to bridge the gap between laboratory experimental work and full-scale commercial operation. The mobile Cobalt-60 irradiator was a very useful tool for the food irradiation program. First and foremost, it was able to take Cobalt-60 irradiation right into the world of future users, and demonstrated that radiation is a safe, reliable source of energy which is simple to use. This unit travelled extensively throughout Canada and the United States where it was used for the irradiation of a wide variety of fruits and vegetables.

The food industry became seriously interested in the irradiation of potatoes after the field demonstrations by the mobile Cobalt-60 irradiator. This led to the first commercial food irradiator which was designed and constructed by AECL for Newfield Products Ltd., a private company located near Montreal, Quebec and began operation in 1965.

Today AECL has developed, manufactured and sold over 2,200 irradiation devices utilizing Cobalt-60 as their energy source. These include roughly 1,700 teletherapy machines, 500 research irradiators, and 75 production irradiators for a wide variety of commercial applications including waste treatment and sterilization of medical supplies.

Irradiator design and operation is a well developed and advanced technology which is presently capable of handling food irradiation on a large scale commercial level.

The irradiator you see before you was designed to process large volumes of produce in pallet boxes. The large carrier size and high speed of this irradiator makes it excellent for low dose applications required in many food processes. In addition to the pallet box irradiator there are several other well established food irradiator designs available.

At the heart of AECL's industrial irradiators is the gamma radiation emitting isotope Cobalt-60. This osotope produced by the nuclear activation of Cobalt-59, has a half-life of 5.3 years, an entirely predictable emission rate of constant energy with excellent penetration, all of which make Cobalt-60 ideal for continuous production processes such as food irradiation. The gamma rays emitted by Cobalt-60 pass through the product being irradiated leaving no residual radioactivity. They simply perform a completely predictable function depending on the dosage and product. Cobalt-59 is activated in the Canadian CANDU nuclear reactors to produce Cobalt-60. These reactors which are operated by Ontario Hydro, one of the worlds largest public utilities, ensure a reliable and steady supply of Cobalt-60 in the foreseeable future.

Experimental work has shown that very low doses of irradiation, 10 - 20 kilorads, will inhibit sprouting in root crops. Radiation doses of 50 to 100 kilorads will eliminate insects and parasites in meat, cereal grains and soft fruits. Doses of 25 to 200 kilorads, will delay ripening of perishable foods such as mushrooms, and a wide variety of soft fruits. Radiation doses up to 1 megarad cause the destruction of pathogens, such as salmonella in poultry. At doses up to 4 megarads, foods can be sterilized for long term storage.

Therefore, food irradiation can be used to stimulate seed germination, inhibit sprouting, slow ripening, eliminate parasites, control infestation, reduce bacteria growth, eliminate pathogens, sterilize hospital meals and make possible long-term storage of food.

A hungry world can not afford to lose 25% of its harvested foods due to spoilage by microbes and pests. This spoilage tends to be largest in developing countries which often have hot and humid climates. The extension of shelf life would also eliminate another major source of food waste by allowing an increased elapsed time between harvesting and final use as a food. This is true of both the soft fruits grown in hot countries and the extension of storage times of root crops in cold countries where only one crop per year can be grown.

Improved seed mutation through genetic effects induced by radiation has the potential to produce varieties with increased yield and reduce germination times. The control of insect populations is another pressing problem in food production. The ravages due to the Mediterranian fruit fly, the Mexican fruit fly, and other insects, cuased the loss of food worth billions of dollars per year. The sterilization of male insects through radiation is proving to be an effective control technique and enables a reduction in the amount of poisonous insecticides which are required.

In addition, radiation can be applied through virtually any type of packaging materials; this is not the case with heat or gas processing. Radiation can thus, if desired, be applied after packaging, as the final process step. In The Netherlands, for example, empty milk and cream cartons are made bacteria-free by radiation processing before they are filled with sterilized milk in order to prolong their shelf life. Foods can be treated in their natural state, with minimal rise in temperature. This can be important because the eating habits of many countries require food to be available in its most natural form. Irradiation can help the food chain at many stages right from initial seed germination to final preparation of meals!

As I have pointed out all of this is technically possible. Why then, you might ask, if food irradiation is so beneficial is it not being utilized on a world-wide basis?

The introduction of a new food treatment process requires international agreements on the legislative, trade and scientific matters. These decisions are not easily arrived at, as has been demonstrated in many countries. Examples are the sometimes conflicting statements of consumer advocates, industry representatives, politicians, scientists and other public interest groups over issues such as cyclamates, saccharin and red dyes in meat. Many foods, in bulk or packaged form, cross international frontiers, making necessary international agreements on the wholesomeness and approvals of irradiated foods. As a point of interest it should be noted that few if any conventional food processes now used on a large scale such as canning or freezing had to undergo the extensive investigations for wholesomeness, public health or consumer acceptance and legislative approval prior to their introduction.

The Joint Expert Committee on Food Irradiation was established by the United Nations in the early 1960's. There were meetings held in 1964, 1969 and 1976 which culminated in recommendations being sent to the Codex Alimentarius Commission. This Commission has over 120 member countries and its major objective is the promotion of international trade. This Commission established standards for quality and wholesomeness of irradiated foods.

There are, in addition, other important areas requiring international agreements. The legal aspects, such as the enforcement of regulations and the acceptance by one country of foods irradiated in another, are particularly important. These topics have been studied at two meetings, in 1972 and 1977, of a consultative group on the legal aspects of food irradiation. The final recommendations after the second meeting were positive and noted that "numerous countries desire that irradiated food be made available because of the obvious advantages of such foods".

The last Joint Expert Committee meeting took place in November of 1980 and it is important to recognize that their report, which has already been acted upon by the Codex Alimentarius Committee on Food Additives, examines food irradiation in a different manner to earlier Joint Committee Reports. Rather than considering and approving individual food categories, the report, after dealing with broad technical areas such as radiation chemistry, microbiological, nutritional and toxicological effects, has concluded that irradiation of any food up to an average dose of one megarad is safe. This shift in emphasis from individual irradiated foods to irradiation processing of food has been reflected in the amended recommended standard now proposed to the Codex Alimentarius Commission. Adoption by the Commission and eventually its member countries of these 1980 Joint Committee Recommendations will permit general acceptance of food irradiation on all suitable food products.

Although it is in the developing countries that the need is greatest and where the most work is required on food irradiation techniques, standards and clearances, it is very important that the major industrialized countries take a leadership position in the application of food irradiation.

The United States issued, earlier this year, a food and drug administration draft policy for irradiated foods which follows the intentions of the latest international recommendations.

It is thus apparent that the legislators and the international bodies have completed their initial tasks and the way is now clear for a rapid increase in large scale application of food irradiation technology.

One other criteria must be assessed, the economics of food irradiation. In this era of inflation and rising costs consumers can not afford to purchase irradiated food products if their purchase price is driven out of reach. Governments, and the food processing industry, must be convinced of the economic savings possible with food irradiation. To assist with this, AECL has sponsored the International Panel on the Commercialization of Food Irradiation, with representation from both the radiation and food processing industries. The object of this Panel is to take food irradiation from the research lab to full commercialization.

The work of this Panel, plus the experience gained by AECL and our customers in building and operating around 75 large scale irradiators world-wide, is showing that the application of food irradiation will not add appreciably to the overall cost of food, in fact the reverse may be true. If the costs to society of wasted or spoiled food, or for hospital care for patients with salmonella poisoning, or the reduction in the gross national product of many developing nations caused by reductions in their exports of bulk food crops, are taken into account, the economics of adding food irradiation can be readily justified.

Economic analyses already carried out show, for example, that the benefits or savings from papaya disinfestation and mushroom preservation are greater than the added costs by four or five to one. It has been estimated that the total operating costs for sprout inhibition of onions and potatoes varies from 0.9 to 3.2% of the final price, depending upon the throughput capacity. The similar number for the extension of shelf life for fresh fish is from 0.2 to 2%.

In closing, I would like to point out that it can be readily shown that gamma radiation processing is extremely energy efficient and compares favourably with conventional food preservation methods. The equipment used to systematically expose produce to the gamma source is simple to operate and easy to maintain - all in all gamma radiation processing is an excellent well established technology which can significantly contribute towards making more food available at reasonable cost to meet the needs of the world's rapidly growing population.

An Overview of the Most Promising INDUSTRIAL APPLICATIONS of GAMMA PROCESSING

By THEO OUWERKERK

MARCH 1982

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An Overview of the Most Promising Industrial Applications of Gamma Processing

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PAPER PRESENTED
at
INTERNATIONAL SYMPOSIUM
on
APPLICATIONS AND TECHNOLOGY
of
IONIZING RADIATIONS

College of Science
KING SAUD UNIVERSITY

RIYADH
SAUDI ARABIA

12 - 17 March 1982

Gamma Processing has a dynamic future as an industrial process. The growth rate of established applications demonstrates the determination of the radiation industry to prove to mankind how much it has to offer.

Numerous promising applications are evolving as a result of an unprecedented joint effort of researchers throughout the world.

The technology is recognized by industry and processes are being developed which are beneficial to countries in all stages of industrial development.

THE FOUNDATION

Gamma Processing has now obtained its well deserved recognition as an industrial process, especially through the sterilization of disposable medical supplies.

While it has been in use for over 20 years, its acceptance was not immediate. Time has, however, brought recognition by authorities and established both reliability and cost effectiveness.

So acceptable is the process that there are currently over 100 gamma sterilizers installed in 38 countries, sterilizing an estimated 30% of all medical disposables produced, worldwide. This market share is ever increasing. More than 10 new gamma sterilizers are installed annually, with ever increasing maximum capacities and initial source loads. The latter are currently averaging 750 kilocuries of Cobalt 60 and we estimate that this could double in this decade.

Cobalt 60 is, as you know, the most commonly used isotope in general gamma processing, and particularly in gamma sterilization. As early as the 1950's, Atomic Energy of Canada Limited, Commercial Products (AECL-CP) recognized the potential of gamma processing and began directing major efforts toward the efficient production of Cobalt 60.

The vehicle is the Canadian Candu reactor. This reactor is not only an efficient producer of electricity, but also of Co60.

The demand grows. In the early 1970's AECL-CP had a modest annual production rate of two megacuries. Now, however, we ship over 15 megacuries annually, and by the year 1990, we will have a total annual production capability in excess of 60 megacuries. This production represents the capability of servicing projected operational Cobalt 60 irradiators with totally installed sources in excess of 500 megacuries. AECL-CP anticipates that by the year 1990, 250 megacuries of these will be dedicated to gamma sterilization. Economic factors are often considered the major hurdle to further growth. Radiation equipment is definitely more expensive than traditional sterilizing equipment, but that does not mean that the cost per unit product has to be higher. Once an adequate volume is established, the cost per unit is very competitive. For example, the average gas sterilization cost of \$20-30 per m^3 can be beaten by gamma sterilization at volumes of over 8000 m^3 per year. Our clients achieve unit cost as low as \$6. per m^3 with our irradiators.

In addition to the favourable economics, gamma sterilization is a reliable process which offers reproducible results. The process does not require the use of hazardous chemicals: the energy consumption is minimal. Gamma sterilization offers health authorities, worldwide, the alternative to impose restrictive regulations on the use of the hazardous ETO Sterilization process.

Furthermore, the process has been fully 'R&D-ed'. The effect of irradiation on materials no longer represents a problem. In addition, the microbiological results are so favourable that the process has set new standards for achievable sterility levels and sterility control statistics.

The introduction of gamma sterilization of medical disposables in your country, therefore, could establish, for you, a solid foundation for the introduction of other gamma processing applications.

As an example, our hosts in Saudi Arabia are currently building their second gamma sterilizer. These 2 plants will provide the necessary service capabilities to develop other promising applications of the process.

Future applications, such as I am about to discuss, will certainly benefit from the design and service capabilities now readily available and from the assurance of adequate Cobalt 60 supply. The most promising and most appealing new application is food preservation.

FOOD IRRADIATION

> "'Post-harvest losses of cereals and legumes in 1976 could have fed almost 170 million people,' says the National Academy of Sciences. Assuming a 10 percent loss of grains and legumes, and a 20 percent loss of vegetables, fruits and roots, NAS predicts that by 1985, food losses will total at least 107 million tons of food worth about $11.5 billion." (Food Development, November 1981).
>
> Have the post-harvest losses in your country ever been quantified?
>
> Do you realize how much food your country has to import as a result of spoilage during storage?

In many countries these losses exceed 30% of crop yields. Worldwide efforts to improve the yield of crops have been successful. Little has been done, however, to preserve the product.

Are you aware that gamma processing is a viable process which can control or eliminate pests, which cause post-harvest losses?

As a result of 25 years of research in food irradiation the process is proven safe; and has much to offer to the food industry. Benefits of the process include:

- low energy consumption
- an environmentally clean process

- reduction of the use of food additives, fumigants and pesticides
- a reliable process
- simplicity in irradiator operation.

Gamma processing has only been commercially implemented on a small scale to date. The benefits of the process, however, are receiving increasing attention worldwide. Factors which have inhibited worldwide commercial implementation of the process include:

- the absence of regulations
- the low energy cost of traditional processes
- the unavailability of specific packaging materials
- the acceptability of fumigants and pesticides.

A drastic change of the economy in the seventies, however, caused the food processing industry to reconsider the use of the traditional energy intensive pasteurization processes and to look for methods of reducing distribution losses. Creativity was required to satisfy the demand for fresh produce, in an environment of suspicion about chemical preservation techniques. In addition, for many countries the price of pesticides and insecticides became prohibitive. This frustrated programs to improve crop-yields, and handicapped the export of fresh produce. Gamma processing offered a solution to problems at hand, but the lack of national and international regulations hindered the implementation of the process. International trade in irradiated commodities still remains difficult today. Despite this, some bilateral trade has evolved.

A recent breakthrough will certainly enhance this activity. The Codex Alimentarius Commission, a joint committee of the FAO and WHO has formulated recommendations which should facilitate international trade within a few years.

In this respect, it is important to note that it is of eminent importance that the Health Authorities in your countries endorse the Codex' recommendations. Your input will contribute greatly to establish complying laws and regulations.

To date, most countries have worked out their own laws independently. Over 40 different food products have been cleared in more than 25 countries. Some products, such as potatoes, have been cleared by most of these 25 countries. Some countries, e.g. the Netherlands, have approved as many as 20 other commodities. A petition procedure for individual products is necessary as most countries still regard food irradiation as a food additive. If we adopt the recommendation of the Expert Committee of the FAO, WHO and IAEA to accept food irradiation as a process (Dec. 1980), this petitioning of products will become unnecessary. The Recommended International Standard for Irradiated Foods issued by the Codex Alimentarius Commission in 1981 comprised the following foods:

Chicken	up to 700 krad
Cocoa Beans	up to 500 krad
Dates	up to 100 krad
Mangoes	up to 100 krad
Onions	up to 15 krad
Papaya	up to 100 krad
Potatoes	up to 15 krad
Pulses	up to 100 krad
Rice	up to 100 krad
Spices, condiments	
dehydrated onions	
onion powder	up to 1 Mrad
Strawberries	up to 300 krad

Most of the recommended applications are aimed at the disinfestation of staple products. It is an attempt to offer the UN-Member States the proven option to attack, as soon as possible, the problem of post-harvest losses.

Other food irradiation effects which can be accomplished at distinct radiation doses include:

- inhibition of sprouting	6 - 15 krad
- disinfestation	20 - 100 krad
- control of parasites	20 - 200 krad
- shelf-life extension	200 - 500 krad
- extended refrigerated storage	200 - 500 krad
- elimination of pathogens	300 - 700 krad
- reduction of microbial load	up to 1 Mrad
- sterilization	over 1 Mrad

In attempting to assess their industrial potential over the next five years, we have to look at the cost and benefits involved. The following tables list the most promising applications, as we project them.

DEVELOPING COUNTRIES

Product	Radiation effect	Benefit	Cost(estimated)
Cereals/Rice	disinfestation	prevent post-harvest losses	$ 3 - 6/ton
Fruit	disinfestation and shelf-life	prevent post-harvest losses and export	$ 2 - 6/ton
Fish	ext. shelf-life	export	$40 -70/ton
Cocoa	red. of micro-biological load	export	$60 -75/ton

INDUSTRIALIZED COUNTRIES

Product	Radiation effect	Benefit	Cost(estimated)
Poultry	elimination of salmonella	food safety	$40 - 70/ton
Spices	disinfestation	quality	$ 3 - 6/ton
Spices	red.micro-load	quality	$100 - 150/ton
Fish	el.salmonella	food safety	$40 - 70/ton
Fish	ext.shelf-life	shelf-life	$40 - 70/ton
Fruit	ext.shelf-life	shelf-life	$ 2 - 6/ton
Fruit	el. fruitfly	quality	$ 2 - 6/ton

AECL-CP does not anticipate an immediately successful role for gamma processing for all these commodities. What is regrettable is that the developing countries who can potentially reap the largest benefits of the process will likely wait until the industrialized world has implemented it. AECL-CP does, however, foresee a modest commercial start for some of these products within a few years. To make some applications even more feasible the combination of an irradiation and traditional treatment often results in a synergistic effect. Currently, the food processing market utilizes less than 2 MegaCuries of Cobalt 60 per year. AECL-CP anticipates that in ten years the source requirements of the food industry may surpass that of medical product sterilization. To date there are 5 - 10 industrial food irradiators installed and operating worldwide, each loaded with a source in the order of approximately a few hundred thousand Curies of Cobalt 60. Currently, AECL-CP has several more under construction; two of these will have 3 million curie capacities. Fortunately, we understand that there are 5 pilot food irradiators under construction in developing countries.

AECL-CP has sponsored the International Panel on the Commercialization of Food Irradiation. With representation from both the radiation and food processing industries, the Panel is addressing all the criteria involved in the commercialization of this process. AECL-CP, our Customers and the Panel all confirm that food irradiation is no longer an "if" but simply a "when".

We want to share our 'know how' with you and to assist you in performing feasibility studies on products you have in mind.

DECONTAMINATION OF FOOD WASTE AND GARBAGE FROM INTERNATIONAL AIRPORTS AND SEAPORTS

Do you know that your country is constantly invaded by dangerous foreign microorganisms? Particularly dangerous is the invasion by viruses as they cause disastrous animal diseases such as African Swine Fever and Hoof-and-mouth Disease. Outbreaks of ASF in the Dominican Republic, Haiti and Brazil, in 1978, caused worldwide alarm. Infected swine had to be killed and the repopulation cost these countries over $40 million. Carriers of the contagious organisms are imported animals, animal products, arriving passengers, imported food, food waste and garbage. Sanitary control and inspection of most of the products crossing the border has been improved in most countries; but severe leaks remain.

Governments involved are often not aware of deficiencies. Imported food waste and garbage dumped at international seaports and airports, represent one of these deficiencies. Collecting and sanitizing systems are available in most of the countries but there is a lack of effective destruction equipment or incinerators.

The Latin American Regional Office of the FAO stated in FAO Bulletin nr/9 (January, 1982):

> "These problems might be greatly reduced by installation of facilities to sterilize waste material by gamma irradiation instead of attempting, often unsuccessfully, to destroy it."

In addition to the food remnants, international airlines even dump the unused meals at airports. Both could easily be used as animal feed after gamma processing. Large international airports, such as London, Frankfurt, New York and Mexico City accumulate as much as 50 tons of food per day. A radiation dose of about 1.5 Mrad would be enough to kill all the bacteria in the waste and thus assure that no dangerous viruses enter the country.

A gamma irradiator could process complete trolleys as they come off the planes. In this way kitchen personnel would be safeguarded when emptying or cleaning the trolleys.

Recently, AECL-CP performed a feasibility study for the decontamination of waste at the Toronto International Airport. Results indicate that 10-20 tons of waste per day is sufficient to make this process economically viable.

If you would like to know more about the FAO program, referred to, or would like to obtain more information on the feasibility of waste processing in general, we would be pleased to make this information available to you.

GAMMA PROCESSING OF FOOD WASTE

Waste, produced by food industries in ever increasing quantities, represents problems to all of us and our environment.

Microorganisms in these products are often harmful to humans and livestock. Some remnants require special treatment before they can be dumped safely. Not only do we spend money dumping these products; but in the process we destroy a valuable food resource.

Why don't we turn this waste into a resource?

We could then reduce the price of foods and avoid costly waste disposal problems. We have the technology. With radiation doses of several megarads we can not only kill microorganisms, but also enhance enzyme hydrolysis processes to produce valuable end products. This process would be especially effective for food industries which generate useful waste in large quantities.

> An example: Molasses from the sugar production. It is well known that molasses can be converted into alcohol through an enzymetic process. That the sensitivity of molasses to the action of enzymes can be changed through gamma processing, however, is a little known fact. Similarly, irradiation of polysaccharides, the starch of wheat, maize, potato, rice, rye, as well as amylose and amylopectin all show this effect.

In the case of molasses, irradiation causes fiber disintegration in the bagasse and makes the produce more soluble in water. With the help of swelling agents, this whole treatment can be further enhanced. Enzyme hydrolysis at this stage is very effective in the forming of the desired fermentable sugars and, ultimately, alcohol.

The alcohol, although too often used for human consumption, is destined to be used as a fuel. Another example is the use of cheese whey. Enzymetric hydrolysis will produce butanol, an important component in the synthesis of fuels. The dairy industry is now generating cheese whey in such quantities that alcohol can be produced in industrial volumes.

The radiation dose to be applied is high. In the case of a dry waste product, such as the sugarcane bagasse, the dose has to be in excess of 10 Mrad to be effective. Swelling agents may help to reduce the required dose; but, the viability of this application will be greatly determined by the cost of the high dose treatment and the need for chemical agents.

In this respect, the cheese whey may have a better chance because doses between 3 - 5 Mrad have been found sufficient to significantly enhance the fermentation process. By applying this dose we coincidentally eliminate the bacterial contamination and prevent competition between bacteria and the enzymes which are subsequently added.

Despite the high dose required and the fact that this application requires more 'R&D' work, we feel it is promising. Waste generated by the food industry represents an ever increasing problem to society, and alcohol, as a fuel, is increasingly in demand.

This application will soon find industrial application.

RADIATION APPLICATION IN SLUDGE MANAGEMENT

The average Canadian citizen produces 100 gallons of sewage per day. Although this sewage contains very few solids, Canada is confronted with an annual production of 1 million tons of sludge. In the U.S.A. and Europe the annual sludge production amounts to 10 million and 5 million tons respectively.

With sludge volumes expected to increase significantly over the next few years, the need for a management plan can easily be demonstrated. This plan not only has to eliminate unsafe sludge distribution; but it must also cover the protection of the public from toxic substances and pathogens. If rendered safe, municipal sludge can be re-used as a fertilizer, soil conditioner or animal feed supplement.

Management regulations have improved over the years; and unsafe dumping fortunately will become more difficult in the coming years.

If an irradiation treatment is used in conjunction with a treatment to stabilize the sludge, such as digestion, it will be possible to freely use sludges through the recycling options.

Raw sludge contains over 10^8 microorganisms; the gram negative bacteria represent 10^4 - 10^7 germs per ml, salmonella 1 - 10 per ml and viruses 10^2 - 10^3 per ml. If a digestion process is applied, a reduction rate of 100 to 1000 can be achieved. Elimination of the remaining contamination can be achieved through irradiation with a dose of 300 - 500 krad.

Stabilization of raw sludge is often not followed and processes other than digestion are applied too. In this case the irradiation dose has to be about 1 Mrad to offset the decontaminating effect of digestion.

If the sludge is to be used as a fertilizer or soil conditioner, the components may end up in the food chain. Recycling regulations reflect this situation. In Canada, for instance, a stabilization process is necessary to make any recycling possible and a pasteurization treatment is required to avoid a 6 month waiting period between application of the sludge and use of the land. Consequently, digested, but unirradiated, sludge is only used as fertilizer on parks and along highways. Several countries approached AECL-CP with the question as to whether it would be possible to use raw liquid sewage sludge for a combination of irrigation and soil conditioning. Rendering this raw sewage safe with a dose of about 1 Mrad is very well possible; but the sewage will give off odours. Further, it is questionable whether traditional irrigation systems would work satisfactorily. Solids in the effluent may settle down before they reach their destination. Other spreading techniques may have to be applied. This interesting proposition requires, but also deserves, further investigation.

Irradiation of Liquid Sludge up to (6% solids)

Most of the irradiation experiments have been done on digested liquid sludges. Two well known pilot plants are at:

1) Deer Island (Boston)
2) Geiselbullach (Munich)

At Deer Island a High Voltage accelerator is used, whereas Geiselbullach uses a Sulzer Co60 batch plant. Both of these plants apply doses of about 400 krad.

Provided that the concentration of the most critical contaminants (viruses) are as low as 0-1 germ/ml a 400 krad dose is sufficient. In the United States, however, for various reasons a minimum dose of 1 Mrad is required. The accelerator used at Deer Island is a 1.5 MeV 75 kw machine, making it possible to treat up to 1000 m^3/day with a 400 krad minimum dose.

High power output of such accelerators will be an advantage in treating large volumes of liquid sludge, but the electrons of the machine and the device to make the required thin water layers seem to be vulnerable to this rugged and corrosive environment. Improvements can be made by applying two accelerators facing each other and allowing for a thick down stream of sludge. AECL is developing an accelerator which would combine a high energy (6 - 8 meV) and high power output (up to 200 kw).

The Geiselbullach plant uses a Co60 source to irradiate sludge in batches of 5.6m^3. The plant has a capacity of 650,000 curies and can treat up to 150 m^3 per day with a 400 krad minimum dose. According to waste water treatment plant operators and to researchers who introduced surface injection techniques for liquid sludges, the batch type of irradiator is preferred over the continuous flow type.

To treat volumes of several hundred thousand gallons per day, as required by an average waste water plant, a gamma irradiator should be able to contain a multi-megacurie source. Application of this technique on a worldwide level could easily mean a need for 50 - 100 MCi of Co60 per year.

Irradiation of Solid Sludges (over 40% solids)

Dewatered sludges cannot be irradiated by accelerators, unless energies of 8 - 10 MeV are applied, and unless sludge is presented in layers not thicker than 5 cm.

For example, Sandia Laboratories in Albuquerque, New Mexico uses an inground gamma irradiator to treat bagged composted sludge. It is one of the very few places in the world where a serious attempt has been made to try out the concept of composted sludge processing despite the obvious worldwide application.

In cooperation with the U.S. Department of Energy (DOE) Sandia has also added another dimension by introducing the use of Cs 137 as gamma source. Because Cs 137 is a spent fuel element component from nuclear power plants, the idea of its recovery and use as a resource is appealling to the U.S. government.

The economics of this process are very critical. Most of the sludges now used as soil conditioner or soil amendment are waste products and, consequently, the economics are weighed against the cost of other disposal options. Composted dry irradiated sludge can be sold to consumers at a reasonable price provided that the irradiation cost is controlled. Irradiation of the dry product is cheaper, per ton of dry fertilizer, than treating the liquid sewage; but the cost of drying or composting have to be taken into account too. The following table gives some cost of irradiation and demonstrates the trade-off situation.

Irradiation of Sludge Cost per Ton	1 Mrad (US situation or raw sludges)	0.3-0.5 Mrad (digested sludge)	0,2 Mrad bacteriological control only
1000 ton/day liquid sludge 4-6% solids	U.S. $5-10 ($50-100/dry ton)	$2-5 ($20 - 50/ dry ton)	$1-4
100 ton/day dry sludge 40% solids	$7 - 10	$5 - 8	---

So far we discussed the most promising applications of waste irradiation:

- International food waste and garbage
- Industrial food waste
- Municipal sludge

That does not mean however, that other sources of microbiologically contaminated effluents or wastes have to be neglected.

Research Laboratories
Hospitals
Rural Communities

generate waste which could be gamma processed as well.

The Animal Diseases Research Institute of Canada, extensively researched the effect of radiation on viruses and came to the conclusion that this technique offers a very reliable and reproducible method for the inactivation of viruses in their laboratory's waste effluents. Shortly, the Institute will publish its results. Convinced that this technique offers unique advantages over traditional inactivation processes, researchers proposed the use of a gamma processor in their planned laboratory in Ottawa.

Public Works, Canada, analyzed the economics and concluded that both investments and operating cost involved are drastically lower than those for traditional comparable systems.

PROCESSING OF CHEMICALS

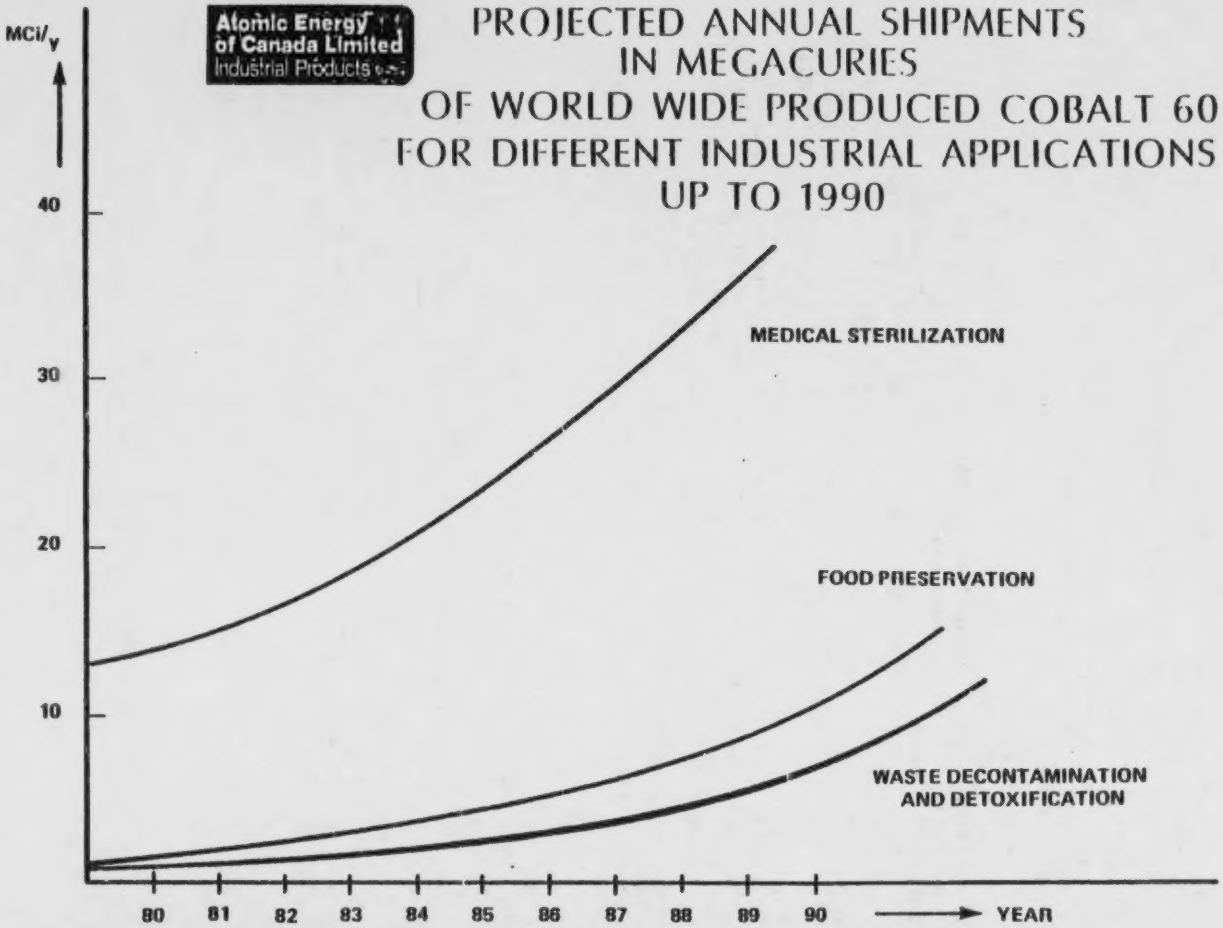
All the promising applications we discussed, so far, use gamma radiation for the control or elimination of harmful microorganisms in food or food by-products.

One process which could have a great impact on mankind, but does not fall under this category, is the detoxification of chemical wastes. Industrial chemical wastes such as P.C.B.'s pesticides and stackgases represent substances which are a threat to human health. Recent estimates put the amount of this waste produced annually in the US alone at 60 million tons. Cleaning it up is estimated to cost over $50 billion per year. Conventional detoxification processes do not work very efficiently, are energy intensive and are often unreliable. The use of ionizing radiation represents a novel approach, which has the potential of being a clean, automatic, self-contained method. Transformation of the toxin to non-toxic components does not change the physical form or volumes of the products involved. Careful selection of irradiation conditions, using additives and an optimum dose-rate, can markedly enhance the efficiency of the radiation process. This selection still requires 'R&D' work, but could be in industrial use by the second half of the 1980's.

IN CONCLUSION, gamma processing will contribute to increased standards of our day-to-day living. Public Health will be improved, food losses will be reduced, the environment will be protected and wastes will be turned into resources.

In order to provide these benefits to our countries we must, through our research and determination, work together and convince our authorites and industries to implement these promising applications.

1982 March 1



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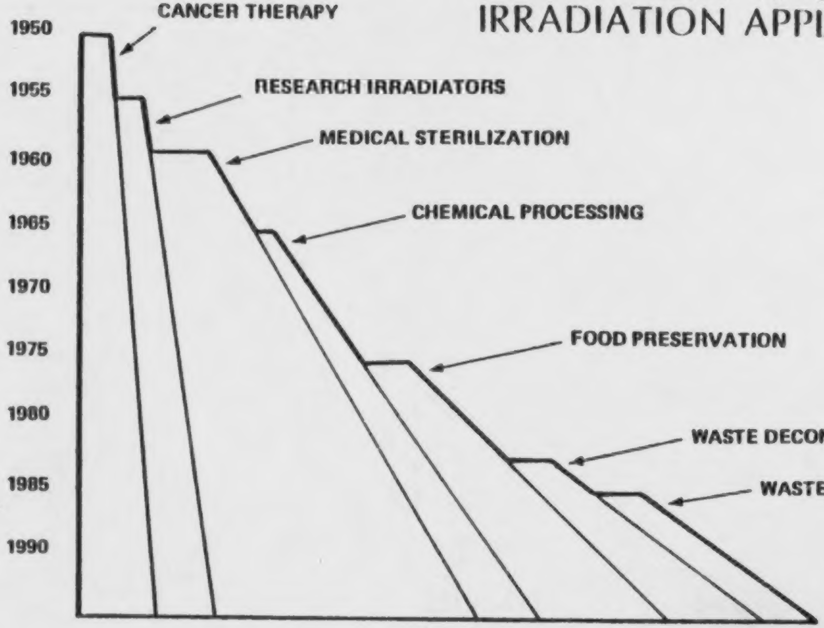
PROJECTED ANNUAL SHIPMENTS
IN MEGACURIES
OF WORLD WIDE PRODUCED COBALT 60
FOR DIFFERENT INDUSTRIAL APPLICATIONS
UP TO 1990

DEVELOPMENT of COBALT 60 IRRADIATION APPLICATIONS



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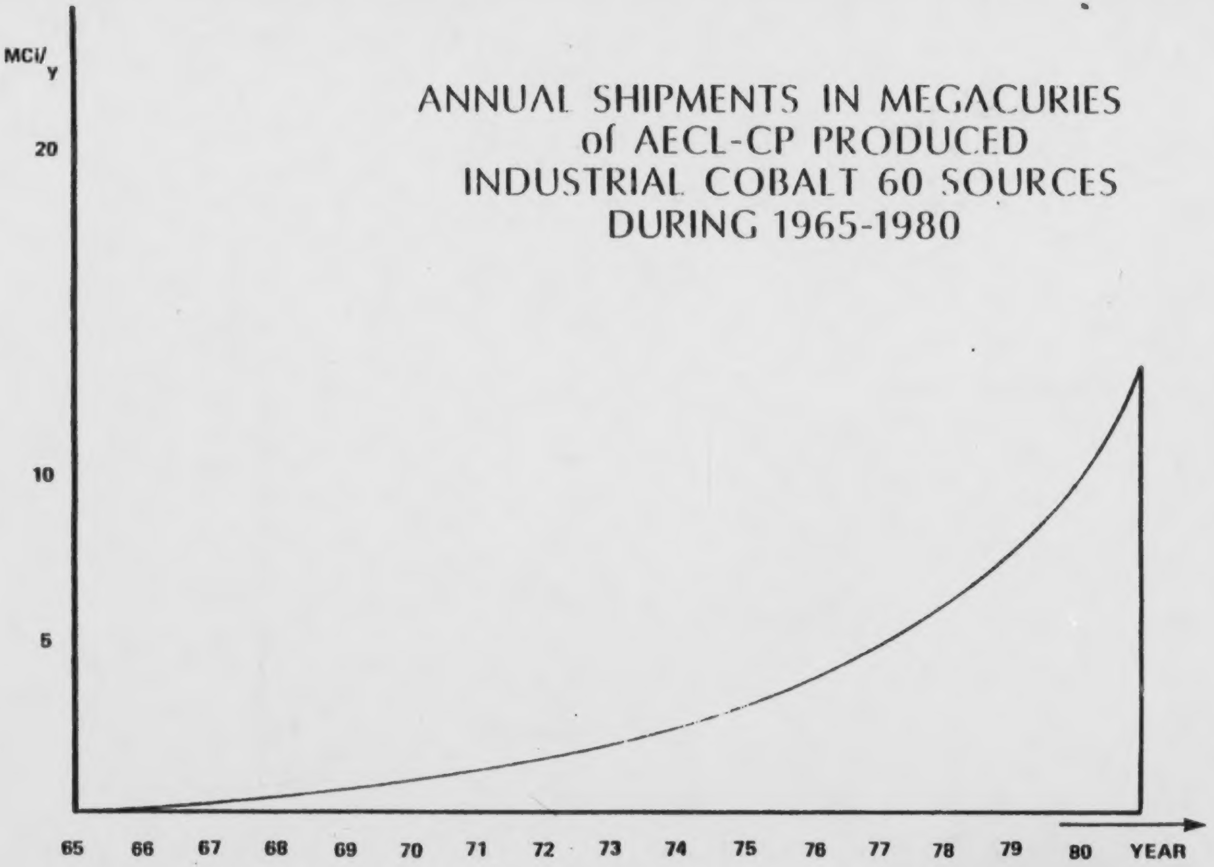

ANNUAL SHIPMENTS IN MEGACURIES
of AECL-CP PRODUCED
INDUSTRIAL COBALT 60 SOURCES
DURING 1965-1980

Atomic Energy
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Industrial Products

NATIONAL PORK
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STATEMENT ON IRRADIATION OF PORK
FOR
COMMITTEE ON SCIENCE AND TECHNOLOGY
SUBCOMMITTEE ON ENERGY, RESEARCH AND PRODUCTION
CHAIRPERSON, CONGRESSWOMAN MARILYN LLOYD

The National Pork Producers Council appreciates this opportunity to provide a statement on the technical infrastructure related to irradiation of pork for inclusion in the record. We commend the subcommittee for bringing together those interested in irradiation of food and we look forward to receiving the complete report.

NPPC represents virtually all pork producers in the U.S. Our 110,000 pork producer members makes our's the largest single agricultural commodity organization in the world. Our mission is to enhance the producer's opportunity for a profit. We see the total elimination of the threat of trichinosis in pork as one way for producers collectively to realize greater profits.

Two years ago, NPPC formed a task force on trichina-safe pork. This group set a goal of a 100 per cent retail pork supply guaranteed safe from trichinosis by 1987. The task force is made up of representatives of three different departments of government with a fourth department providing consultation. There are representatives of six government agencies working closely with industry to solve this national problem.

While the task force is developing and reviewing many different avenues to approach this problem, low-dose irradiation of pork has demonstrated real possibilities. In fact, one commercial company is so convinced of its merits that they have submitted a petition to FDA requesting approval of the process for elimination of trichina from pork. Also, NPPC has initiated or cooperated in numerous studies and surveys relative to pork irradiation.

We commend the Department of Health and Human Services and the Food and Drug Administration for their February 14 proposal to allow low-dose irradiation of certain foods. We believe this is a real step forward in the recognition of the potential for irradiation of food. It is long overdue. We are encouraged by the position that irradiation at levels not to exceed 100 kilorads (krads) is safe, and we believe it is a realistic approach. We, therefore, commend the Department and the Agency for this significant advance in regards to the irradiation of food.

The NPPC was disappointed that the proposal made no reference to the irradiation of pork. Representatives of the NPPC had several meetings with the staff members of the Food and Drug Administration to discuss pork irradiation. We were hopeful that the discussions and the evidence the Agency had would be sufficient to include the irradiation of pork in the proposal. We now understand that the staff did not consider sufficient the data and information that it had. Therefore, we have submitted much data that assures the efficacy of low-level irradiation to make pork trichinosis safe and that the product is not affected adversely by the irradiation.

The Agriculture Research Service and the Department of Energy has supplied to the Food and Drug Administration as a comment on the February 14 proposal, the summary of the research conducted to demonstrate the efficacy of irradiation in the sterilization of the trichina parasites. It is clear from the research that has been conducted and as reported, that 15 krads is sufficient to inactivate the trichina organism. This is so far below the limit of 100 krads, which the agency has proposed as being considered safe, that we believe it should be favorably considered.

So as to provide an ample margin of safety, 30 krads is being proposed. A summary of the research being conducted in regard to the organoleptic, microbiological, and dose response effects resulting from irradiated pork has also been submitted to the Agency by the U.S. Department of Energy.

The NPPC has conducted a survey in an effort to determine the attitude of consumers in regard to irradiation of food. We are attaching to our statement a copy of the report of this survey entitled, "Consumer Reactions To The Irradiation Concept." It is reassuring to note from the report of this survey that while a significant proportion of the consumers were concerned about irradiation, the percentage was less than were concerned about the alternatives, e.g., preservatives, chemical sprays, food waste and spoilage, and food-borne disease. This survey of consumers reaction to irradiation is the only one that has come to our attention. Therefore, and since it pertains to the irradiation of food, not just pork, we are furnishing this subcommittee with a copy of the report. We believe it will be helpful for this subcommittee to receive this up-to-date survey of consumer opinion. We certainly hope the results of this consumer survey will be reassuring in regard to the consumer's reaction to the irradiation of food.

We agree with the Agency's conclusion that 100 krads can be established as a safe level of treatment; that this level cannot make food radioactive, and this cannot expose the consumer to radiation. The difference in the chemical constituents of irradiated foods processed at these low doses and non-irradiated foods, is too small to affect the safety of the food. Food irradiated at these low doses will not have its nutritional value changed. The balance between microbial spoilage organisms and the botulism organisms is not adversely affected by these low doses. This would be especially true at the levels that we're recommending for the irradiation of pork, which are much less than the 100 krads. For all of these reasons, we believe that the irradiation of pork is safe. We are convinced that the identified effects can be achieved and that there is no hazard to the consumer from pork that has been irradiated in this manner.

We have been assured that if a food irradiation regulation is promulgated to provide for the irradiation of pork, that the Food Safety and Inspection Service (FSIS) of the USDA can be depended upon to enforce such a regulation. This is important because the plants in which such a process would be used are regulated by the FSIS. This assurance has been communicated to FDA from FSIS.

We recognize there is a need for data in regard to the design of the irradiation treatment chambers that must be met to provide for safety of persons working in plants where irradiation will be conducted. We have been assured that such safety features can be specified by the Nuclear Regulatory Commission (NRC) and the Office of Safety and Health Administration (OSHA). We believe the details in regard to the installation, construction, and operation of the irradiation equipment are state-of-the-art engineering details which can be provided by the staff engineering organizations that would be called upon for installation of the irradiation treatment.

The NPPC was an active supporter of the legislation introduced earlier this year by Congressman Morrison with many cosponsors (HR5605). We strongly supported and still support the regulation of irradiation as a process rather than a food additive.

When the February 14 Food and Drug proposal entitled "Irradiation in the Production, Processing, and Handling of Food" was published recognizing the irradiation at 100 kilorads or less as safe, we were of the opinion that the legislation was not as critical. This view was supported by reports from the FDA that the proposal was in fact intended as a "generic" food additive regulation. We were told that the irradiation of other foods below the 100 krads could be accommodated under this proposal in addition to those specificaaly specified for fruits and vegetables and disinfestation of insects.

However, later discussions and correspondence have raised questions as to the breadth of the application intended by this proposal. While reference is still made to other irradiation processes that may be approvable at the low levels, we are also told that it may be more expeditious for the NPPC to submit a food additive petition. We believe strongly that it is highly desirable not to have every use of the irradiation at this low level to be covered by individual food additive petitions. Therefore, we support legislation which would eliminate this need for individual food additive petitions and would be conducive to the broader application of irradiation to foods at the low, safe levels.

We therefore wish to be on record as supporting the legislation that would make it less expensive to secure the approval of the irradiation for food products, especially at these low levels which are recognized to be safe by the Food and Drug Administration. We will be pleased to support this concept of the legialation. When hearings are held on this legislation which we have been assured will be held, we will wish to testify and make specific recommendation on the legislation being considered.

Ms. Chairman, we appreciate this opportunity to submit our views in regard to irradiation. We believe strongly that the obstacles to approval of food irradiation should be eliminated. As I'm sure will be brought out by other witnesses, other nations and several international organizations have recognized the effectiveness, practicality and safety of food irradiation. We believe, therefore, that it is high time that our own government, and specifically the Food and Drug Administration, take cognizance of this trend and move in concert with the governments of other nations and international organizations to approve the use of irradiation for food.

The NPPC wishes to express its appreciation to the Subcommittee for allowing their comments to be part of the record of this hearing.

Respectfully submitted,

Wayne Walter

Wayne Walter
President

CONSUMER REACTION TO THE IRRADIATION CONCEPT

A Summary Report

Prepared for

Albuquerque Operations Office
U.S. Department of Energy

and

National Pork Producers Council

(Contract No. DE-SC04-84AL24460)

Prepared by
Wiese Research Associates, Inc.

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With any effort to summarize or abstract information from a more comprehensive source, interpretation is required on the part of the writer. The analyst must make judgments about what data is pertinent to include and, in this case, must also attempt to present the information in a format that will be useful and actionable from a planning and decision-making standpoint.

Since summaries by nature are not comprehensive, readers of this report cannot anticipate that all findings of potential value will be thoroughly discussed herein. Further, for decision making, a number of interpretations of research findings are almost always possible. Therefore, whenever planning or decision making is taking place, the reader should carefully study all information presented in this report as well as review applicable portions of the complete tabular reference results provided under separate cover. A very large quantity of data has been generated in the reference reports, and WRA would be happy at any time to review specific pieces of information to assist with future decision making.

Any interpretations of the meaning or applied use of data presented in this report represent the professional research opinion of Wiese Research Associates, Inc. All such interpretations are based on a review of the information collected in this study and WRA's perspectives gained from previous research experience for a wide variety of consumer goods and services over the past fourteen years.

The following Summary Report has been organized into four (4) separate sections each dealing with a major informational topic related to the project. These result presentation sections are preceded by a description of the project methodology which follows directly.

Situation

One of the goals of the National Pork Producers Council is to achieve the sale of trichina-free pork by the year 1987. The most promising method for achieving this goal appears to be through gamma irradiation processing. The U.S. Department of Energy has been actively involved with the National Pork Producers Council in studying the feasibility of such processing for the pork industry.

In August, 1983 a feasibility study was completed for the U.S. Department of Energy entitled "Trichina-Safe Pork By Gamma Irradiation Processing" in which the following conclusions were made.

> "There do not appear to be any insurmountable obstacles from the viewpoints of political and social feasibility (for the gamma irradiation). It appears likely the Food and Drug Administration will rule that food irradiated at doses of one hundred krad or less is safe for human consumption. Social feasibility will depend in large part on consumer acceptance of pork certified as trichina-safe and on attitudes toward the irradiation issue."

Additionally, this report suggested that further study is necessary in a number of areas including developing more conclusive evidence on consumer acceptance and preparing a consumer education plan (for the process). As an initial step in providing such information, the National Pork Producers Council, using partial funding by the U.S. Department Of Energy, commissioned a consumer opinion research study and Wiese Research Associates, Inc. was selected as the research firm to complete this study.

Purpose And Objectives Of The Research

The overall purpose of the research project was to collect information from consumers that will be helpful in planning and implementing effective consumer information and education efforts concerning the irradiation process. More specifically, informational objectives were established to identify initial consumer reactions to the irradiation concept, identify concerns that exist in the minds of consumers about the process, explore differences in reaction to the concept given various terminologies or methods of definition, and finally to determine attributes of the process or its use which have the greatest potential for positively influencing acceptance within the consumer public.

The informational objectives identified for the project were subsequently used in the development of a questionnaire. WRA designed this questionnaire with the close involvement and review of the National Pork Producers Council, representatives of the U.S. Department of Energy, and others familiar with irradiation processing. The specific questionnaire development process is outlined in greater detail later in this study description.

Sampling Design

In any research project, it is critically important to accurately define the "population" for study. The population is the source from which all sampling must take place and to which all results must be projected.

For the purposes of this research project, the population was defined as adults age eighteen and above residing within the continental United States. This population was the basis for sampling and represents the total group to which results of this study can be projected.

To insure an accurate and representative sample of the population as defined, WRA utilized a national probability sample based on proportionate representation of randomly generated telephone numbers using known distributions of residence-based phone listings for the entire United States. The generation of the sample was conducted in such a way as to allow the contact of unlisted or unpublished numbers as well as those currently published in directories.

To increase the confidence of obtaining a representative cross-section of the adult U.S. population, quotas were established both by geography and for sex by age population characteristics. Known demographic information for the continental United States was used in establishing these quotas. At each randomly contacted residence, a system to randomly select the adult over the age of eighteen to be interviewed was employed. This system was followed until established quotas required screening for specific categories of respondents.

The total sample size for this national study was one thousand (1,000) respondents. This size of sample is easily sufficient to provide quite precise estimates of total population values and opinions and further is large enough to allow fairly detailed data analysis by key sub-sample clusters or categories of respondents (i.e., geographical areas, age groups, sex, education, household income, etc.). While estimates obtained from appropriately conducted research projects are in most all instances accurate approximations of total population values, they are in fact only estimates and care needs to be taken when interpreting results and making projections. The chart on the following page should be kept in mind when reviewing the results discussed in this report. This chart provides the expected stability level for obtained results for the total sample size of one thousand (1,000) and for various selected sub-sample sizes.

Expected Standard Error Ranges
For Various Sample Sizes*

Sample Size	For obtained results of....								
	10%	20%	30%	40%	50%	60%	70%	80%	90%
1,000:	±1.9	±2.5	±2.8	±3.0	±3.1	±3.0	±2.8	±2.5	±1.9
800:	±2.1	±2.8	±3.2	±3.4	±3.5	±3.4	±3.2	±2.8	±2.1
600:	±2.4	±3.2	±3.7	±3.9	±4.0	±3.9	±3.7	±3.2	±2.4
400:	±2.9	±3.9	±4.5	±4.8	±4.9	±4.8	±4.5	±3.9	±2.9
200:	±4.2	±5.5	±6.4	±6.8	±6.9	±6.8	±6.4	±5.5	±4.2
100:	±5.9	±7.8	±9.0	±9.6	±9.8	±9.6	±9.0	±7.8	±5.9

*At a 95% confidence level. Ranges expressed in percentage points.

An illustration using the preceding chart may be of value. From the study we find that seventy-four percent (74%) of the one thousand (1,000) interviews completed were with the primary food shopper for the household. Using the chart at the approximately seventy percent (70%) obtained result level, we find that we can be ninety-five percent (95%) sure that from 71.2% to 76.8% (74% ± 2.8%) of all respondents we would have interviewed if we had contacted all households in the United States would have been the primary food shopper for that household if we had contacted all households rather than the sample of one thousand (1,000.)

Method Of Sample Contact

All data obtained in this project was collected via telephone. Given the nature of the information desired and budget considerations, telephone was viewed to be the preferable method of respondent contact. Telephone can be an extremely accurate method of collecting such information if properly conducted, and WRA has had the experience to insure proper conduct of telephone surveys.

All contacts were made via a shared WATS system from Omaha, Nebraska. The vast majority of calling took place during late afternoon and evening hours during the week and during the day on weekends. This contact approach allowed maximum contact probabilities and also tended to minimize long-distance expenses by concentrating calling in rate discounted time periods. However, a portion of all calling was completed during daytime hours to allow the opportunity for interview of people not normally home during evening or weekend time periods.

If an initial contact attempt did not result in an interview, a minimum of two additional attempts was made to reach a qualified respondent at that household. This callback regimen was necessary to insure high completion rates so important for projectable findings.

Interviewers

The final results of any research project are only as good as the interviewers who collect the information. WRA used its own staff of mature and experienced interviewers in Omaha to collect all data in this study. These interviewers have had extensive experience in many consumer-related research projects and WRA's standards for techniques and completeness are high. Each interviewer was thoroughly briefed on the final questionnaire prior to sample contact and each interviewer had their work edited at the one hundred percent (100%) level by supervisory personnel. Further, each interviewer's calls were validated at the ten percent (10%) level through supervisory callbacks as well as one hundred percent (100%) verified against actual long-distance calling records.

Questionnaire Development

Asking the right questions is critically important to the value of information obtained from any research project. To insure the development of a final questionnaire that would provide the most useful information possible, the following approach was used in questionnaire design for this project.

Questionnaire Design Process

1- Given the objectives for the project provided by NPPC and the Department of Energy, WRA prepared an initial draft of possible question items.

2- This draft was then submitted to NPPC and was mutually reviewed by NPPC, Department of Energy representatives, and WRA. Based on this review process, revisions were made and this process was continued until all parties participating in the questionnaire development process were satisfied with the final instrument.

3- This final questionnaire draft was then pilot-tested by WRA with a sufficient number of respondents to insure its clarity and workability prior to sample contact.

4- After final revisions were made, approval of the questionnaire by NPPC was obtained and WRA printed all necessary question instruments for this project.

The final questionnaire required an average of about fourteen (14) minutes to administer. A copy of the actual questionnaire used in this study has been included as an appendix to this report.

Data Processing And Analysis

All data collected in this study was edited, coded, input onto disk, verified, and computer processed by WRA. Tabular results were generated for the total sample and for selected categories of respondents (i.e., age groups, sex, household size, household income, educational levels, etc.). WRA's program for generating tabular output includes a Chi-Square statistical analysis to determine where statistically significant trends and differences in findings exist across sub-sample categories. These significant differences at the ninety-five percent (95%) confidence level are indicated in the tabular results when present by double asterisks (**) next to the category heading.

The tabular results and statistical analysis provided the basis for this Summary Report. When combined with the tabular results, this Summary Report represents all products prepared for the project.

Time Frame

Research results are in one way very much like a financial balance sheet. They reflect the situation at a given point in time. Therefore, it is very important to keep in mind when the data was collected for this project as planning takes place and decisions are made using these results. All interviewing for this project was completed during the first half of February, 1984.

Section I Characteristics Of The Sample

It was noted in the description of the study methodology for this project that, in addition to the national probability sampling approach, quotas were established to insure obtaining a representative cross-section of the adult U.S. population by geography and by sex by age characteristics. Through the use of the random probability sampling approach and stratifications matching known population characteristics of geography and sex by age, a high degree of confidence is provided that the sample "listened to" in this project is representative of the adult population in the continental United States.

The geographical areas used for more definitive data presentation in the tabular results are as follows:

New England:	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, Metro New York City
Middle Atlantic:	Delaware, District Of Columbia, Maryland, New Jersey (excluding metro New York area), New York (excluding metro New York area), Pennsylvania (partial), Virginia (partial)
East Central:	Kentucky, Michigan, Ohio, Indiana (excluding metro Chicago area), Pennsylvania (partial), West Virginia
West Central:	Colorado, Illinois, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, North Dakota, South Dakota, Wisconsin, Wyoming
Southeast:	Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, Tennessee, Virginia (partial)
Southwest:	Arkansas, Louisiana, New Mexico, Oklahoma, Texas
Pacific Coast:	Arizona, California, Idaho, Nevada, Oregon, Utah, Washington

The distribution of respondents actually obtained for these areas as well as the sex by age distribution of the sample compared to U.S. population characteristics are presented in Table 1.

Table 1

Comparison Of Sample And Actual Population Profiles By Geography And Sex-By-Age Characteristics

Category	Percent Of Obtained Sample (N=1,000)		Approximate Percent Of U.S. Population*	
Geographic Area				
New England:	12%		12%	
Middle Atlantic:	11%		11%	
East Central:	15%		15%	
West Central:	16%		16%	
Southeast:	18%		18%	
Southwest:	11%		11%	
Pacific Coast:	17%		17%	
Totals:	100%		100%	
Sex/Age				
Males 18-24:	9%	46%	9%	47%
Males 25-34:	11%		11%	
Males 35-44:	7%		8%	
Males 45-54:	7%		7%	
Males 55-64:	6%		6%	
Males 65/Over:	6%		6%	
Females 18-24:	9%	54%	9%	53%
Females 25-34:	12%		12%	
Females 35-44:	8%		8%	
Females 45-54:	7%		7%	
Females 55-64:	8%		7%	
Females 65/Over:	10%		10%	
Totals:	100%		100%	

*Sources of U.S. Population Characteristics
Geographic Area: A. C. Nielsen Company Marketing Research Services Group Territories (adapted for this study)
Sex/Age: 1980 U.S. Census - Total U.S. Population Characteristics - Table 43

A review of the preceding table clearly shows the representativeness of the obtained sample when compared to U.S. population figures.

In addition to sex, age, and geographic characteristics, a number of other respondent classifications were obtained during the interview and used for analysis of findings. These included the educational level achieved by the respondent, the household size, the household income, the size of the community, and whether or not the respondent was the primary food shopper for their household. The distribution for these characteristics found within the total sample is presented in Table 2 on the following pages.

Table 2

Characteristics Of The Obtained Total Sample

Category	Frequency	Percent Of Total Sample
Respondent Sex		
Male:	467	47%
Female:	533	53%
Respondent Age Group		
18 - 24:	184	18%
25 - 34:	230	23%
35 - 44:	153	15%
45 - 54:	139	14%
55 - 64:	139	14%
65/Over:	155	16%
Respondent Education		
Less Than High School Graduate:	128	13%
High School Graduate:	328	33%
Some College Or Formal Technical Training Beyond High School:	297	30%
College Graduate:	170	17%
Post Graduate:	70	7%
Household Size		
One:	189	19%
Two:	325	33%
Three:	184	18%
Four:	161	16%
Five to Six:	105	11%
Seven or More:	27	3%
Household Income		
Under $15,000/Year:	198	24%
$15,000 - $24,999:	216	26%
$25,000 - $40,000:	270	32%
Over $40,000:	154	18%
Household Shopper Status Of Respondent		
Primary Food Shopper:	738	74%
Not Primary Food Shopper:	262	26%

(Continued)

Table 2
(Continued)

Category	Frequency	Percent Of Total Sample
Geographic Area		
New England:	120	12%
Middle Atlantic:	112	11%
East Central:	153	15%
West Central:	159	16%
Southeast:	182	18%
Southwest:	112	11%
Pacific Coast:	162	17%
Community Size		
Over 500,000:	243	24%
150,000 - 500,000:	105	11%
50,000 - 150,000:	152	15%
10,000 - 50,000:	209	21%
Under 10,000:	128	13%
Rural:	160	16%
Totals:	1,000	100%

Percentages totalled vertically to 100% for each category. Respondents not providing information for a specific category not considered in % computations.

In addition to providing a base for understanding the composition of the sample "listened to" in this project, the reader should take particular note of the frequencies or number of respondents interviewed within each of the categories. When using the tabular results and estimating the probable accuracy of findings for any particular sub-sample, a reference to these frequencies and the standard error range chart presented in the Study Description will be most useful.

In summary, the sampling methodology used in this study as well as the characteristics of the total sample obtained suggests that the findings discussed in the subsequent sections of this report are based on responses from a good cross-section of the adult population residing within the continental United States.

Section II Consumer Concerns About Current Food Preservation Treatment Methods, Disease Risk From Food, And Food Spoilage Problems

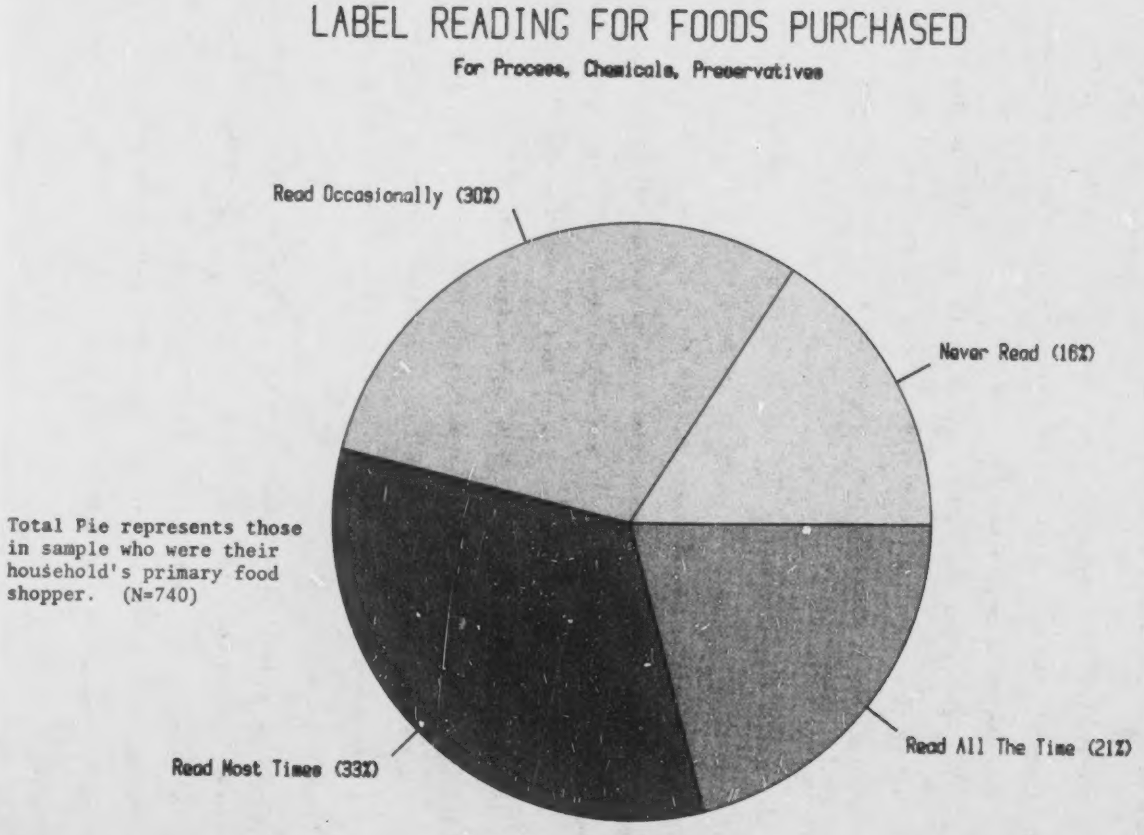
Any evaluation of consumer concerns about the gamma irradiation process for food, if completed without consideration of alternative processing methods and the disease and spoilage problems that necessitate the use of such methods, would be to evaluate the concept in a "vacuum". In the real world, irradiation is one alternative which can effectively deal with the problems of disease or food spoilage, but it does need to be considered in relation to other alternative methodologies.

Using this logic, respondents in this study were asked several questions to gauge their level of concern about the use of preservatives in food and chemical sprays or fumigants as well as their concerns about the risk of contracting disease from food and the problem of food spoilage. This information provides a framework for subsequent analysis of concerns voiced for the irradiation concept.

Also, respondents who were the primary food shoppers for their household were asked if they currently read labels on processed foods that they buy specifically to see what processes, chemicals, or preservatives have been used. This questioning approach provides an indication of the degree of sensitivity consumers have overall at the present time to existing processes and chemicals utilized in processed foods.

Figure 1 on the following page shows the incidence of label reading for processed foods to determine the chemical or preservative content or the food processing technique utilized. Each respondent who was the primary food shopper for the household (N=740) was provided with a four-point scale on which to indicate their frequency of such label reading and Figure 1 summarizes the results obtained for the total sample.

Figure 1



LABEL READING FOR FOODS PURCHASED

For Process, Chemicals, Preservatives

Total Pie represents those in sample who were their household's primary food shopper. (N=740)

In total, only about one out of every six respondents (16%) indicated that they never read the labels of processed foods they purchase. Apparently, the vast majority of food shoppers in this country are reading labels on processed foods at least occasionally and a majority (54%) indicate that they read labels most of the time or all of the time when purchasing processed foods.

These findings seem to imply that a very significant portion of the food shoppers in this country are sensitive to the processes used as well as the chemicals and preservatives incorporated into processed foods that they purchase. Even though consumers' descriptions of their behavior will not always track perfectly with actual consumer behavior, the strength of response for label reading found here almost guarantees that sensitivity in this area is high.

Several significant differences were found in the level of label sensitivity when the demographic categories of respondents were evaluated. Most notably, as educational level increased the frequency of label reading for processed foods increased. For example, over two-thirds of the post-graduates interviewed in this study stated that they read labels on processed food all or most of the time compared to only thirty-eight percent (38%) of those respondents who held less than a high school education. Further, it appears that the youngest individuals, those under the age of twenty-four, were less frequent label readers than their older counterparts. Finally, the frequency of label reading for processed foods varied significantly by geographical area. The highest incidence of frequent label reading was present in the New England, Middle Atlantic, and Pacific Coast areas with the lowest incidence of such reading found in the East Central and West Central regions.

The frequency of consumers reading labels to determine the processes and content of foods purchased would suggest that concern or at least interest exists in a significant number of cases about these issues. The results graphically depicted in Figure 2 on the next page show these levels of concern voiced by all consumers for four issues. These issues as presented to respondents were:

Figure 2 Label Key

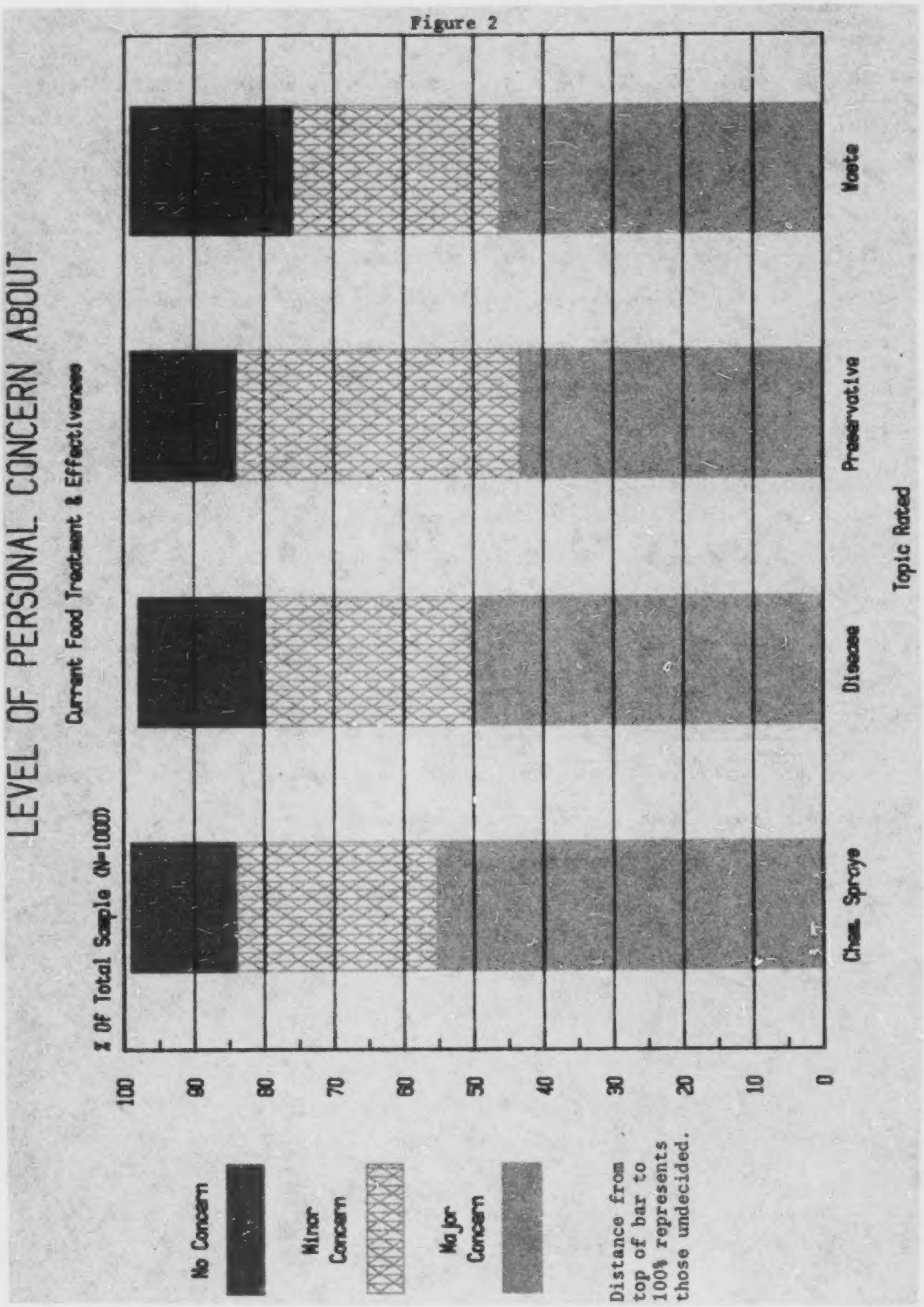
Chem. Sprays: Sprays or chemicals used on some fruits and vegetables that you eat.

Disease: The risk of being ill from diseases in or carried by food that you eat.

Preservatives: Preservatives that are being used in some of the foods you eat.

Waste: The waste from having to throw away food you buy that spoils before you eat it.

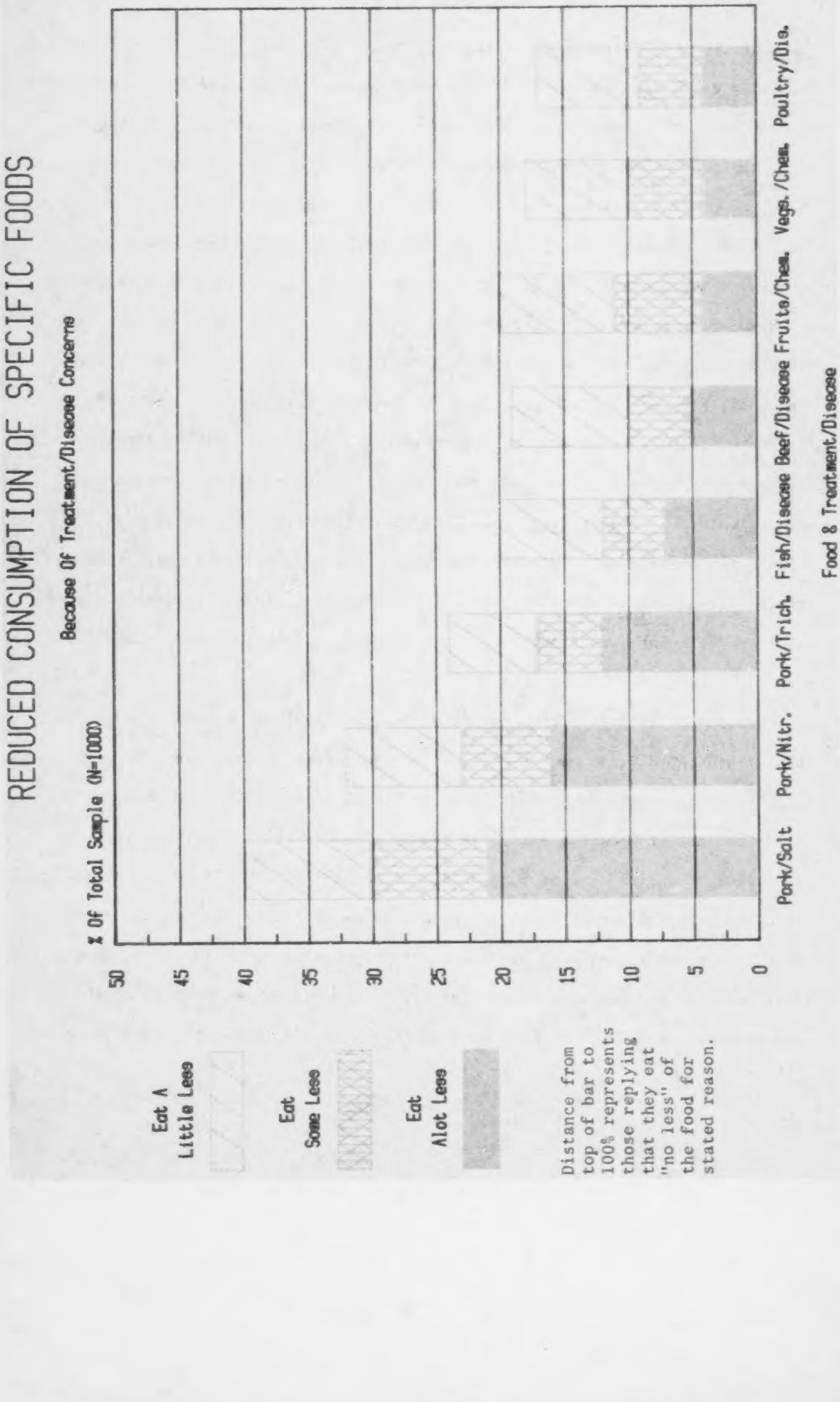
Figure 2


LEVEL OF PERSONAL CONCERN ABOUT
Current Food Treatment & Effectiveness
% Of Total Sample (N=1000)
100
90
80
70
60
50
40
30
20
10
0
Chem. Sprays
Disease
Preservative
Waste
Topic Rated
No Concern
Minor Concern
Major Concern
Distance from top of bar to 100% represents those undecided.

Even a cursory examination of Figure 2 shows that a significant portion of adults in the United States holds a *major concern* for each of these issues. Relatively speaking, concern levels were the highest for chemical sprays used to treat fruits or vegetables and relatively lowest for the waste/spoilage issue. Still, in all four categories over four out of ten consumers indicated a *major concern* and over three-fourths *at least a minor concern*. Without question, the current treatment methodologies of sprays and preservatives as well as the risk of disease and concern about waste or spoilage of food are problems that many consumers consider to be major concerns to them personally.

Generalized concerns are important to understand, but perhaps more important are the potential reductions in consumption of specific products because of concerns about processes or techniques used to combat disease or spoilage as well as the risks of disease or spoilage themselves. To provide some insights into the degree of impact such concerns are having for specific products, a series of eight examples was provided to consumers with each respondent asked if they eat a lot less, some less, a little less, or no less of that particular product because of the specific concern provided. Figure 3 shows that for pork products, concerns about preservative techniques currently in place as well as the risk of trichinosis dramatically limits or reduces consumption.

Figure 3



Distance from top of bar to 100% represents those replying that they eat "no less" of the food for stated reason.

When the total sample is considered, over one out of five respondents stated that they eat a lot less pork than they otherwise might because of the salt content. Four out of ten respondents stated that they eat at least a little less pork than they otherwise might because of this salt issue. Of the specific foods and processes tested, reduced consumption of pork because of the salt content was the one with the apparent greatest negative impact on consumption.

The concern about nitrites in pork also significantly reduces consumption followed by concerns of trichinosis in pork. It is interesting, however, that concerns about the preservatives - salt and nitrites - in pork products are apparently greater limitations to pork consumption than concerns about the disease of trichinosis which the preservatives are meant to help control. Still, nearly a fourth of all consumers in this country could be projected to eat at least a little bit less pork than they otherwise might because of trichinosis concern and these findings would reinforce that the goal of trichina-free pork is certainly one which could meaningfully increase pork consumption. Elimination of salt and preservatives in pork, however, could be expected to increase consumption even more.

Reductions in consumption for fish, beef, or poultry because of concerns about potential disease were not nearly as pronounced as they were for pork. It is also interesting that reductions in actual consumption of fruits and vegetables because of chemical sprays, although measureable, did not approach the reductions in consumption of pork because of preservative or disease issues. Since the level of concern about chemical sprays on fruits and vegetables was previously shown to be quite high (refer to Figure 2 on page 19), the relatively lower level of reduced consumption for fruits and vegetables because of this factor seems confusing. Perhaps many consumers do not translate their concerns to fruit and vegetable purchases because of the lack of labeling or because of their belief that cleansing and preparation can eliminate or reduce concerns that they may have about the sprays being used. In any event, these concerns about chemical sprays do not appear to be manifest in actual consumption reductions nearly as frequently as fears about preservatives are for pork products.

In summary, the irradiation concept is being introduced to a consumer public in this country that is, in the majority of cases, already concerned about existing methods of treating foods and significantly concerned about the risk of disease from foods and the problem of spoilage. These concerns appear to manifest themselves most directly with pork products and there can be little question but that the demand for pork in the United States is artificially limited to a sizeable degree because of consumer concerns about the salt content of pork, nitrites used in processed pork products, and the fear of trichinosis. If these concerns can be significantly reduced, or ideally eliminated, one could logically project that consumption for pork in this country could increase beyond its current level.

Section III — Awareness Of And Initial Consumer Reaction To The Irradiation Method For Food Processing

The focus of this third section of the report is on consumers' reactions to the irradiation concept. In addition to identifying concern levels, findings from specific questioning to determine the exact nature of concerns as well as perceived advantages for the process are considered. Further, present levels of consumer awareness for the concept are described and finally the impact different terminologies have on consumer reaction to the processing concept are explored.

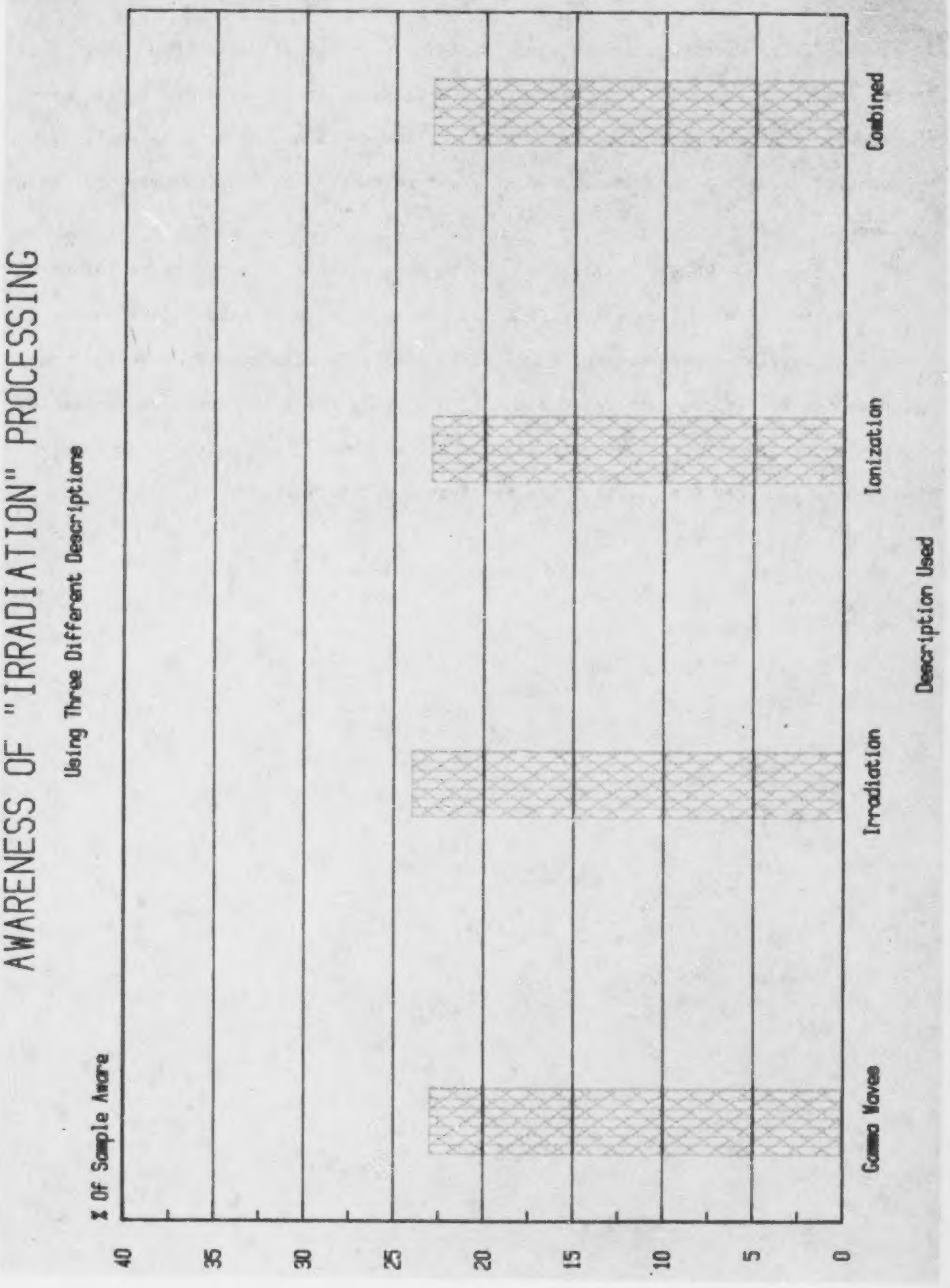
Because the terminology or method of describing the concept of irradiation was one of the independent variables identified for study, it was difficult to arrive at any single definition that could be provided to consumers to convey the concept clearly without impacting reactions by using only one description approach. Therefore, item sampling employing three different but accurate descriptive definitions for the concept was employed in this study. Approximately one-third of the respondents were presented with each of three definitions to obtain their initial reaction to the concept. The three rotated definitions utilized were as follows:

> Gamma Waves: Treating them (foods) with gamma waves, energy like ultraviolet light but more powerful.
>
> Irradiation: A technique called irradiation where foods are treated with low levels of irradiation energy.
>
> Ionization: A technique called ionization where foods are treated with low levels of electromagnetic energy.

The sub-samples of respondents presented with each of the optional concept description terminologies were cross-tabulated independently to allow analysis of results to each item in the study based on the initial definition used. Therefore, it is possible to measure differences in attitudes or response based on initial descriptions employed. Further, for certain analyses the combined reaction using all three terminologies, and therefore the total sample, has been used.

Before any thoughtful planning can be accomplished with regard to consumer information or education efforts for the concept, it is necessary to know the current levels of awareness or familiarity adults in this country have for the concept. Therefore, each respondent in this study was asked their awareness for the concept and Figure 4 graphically summarizes these results for those sample segments provided with each of the three optional definitions.

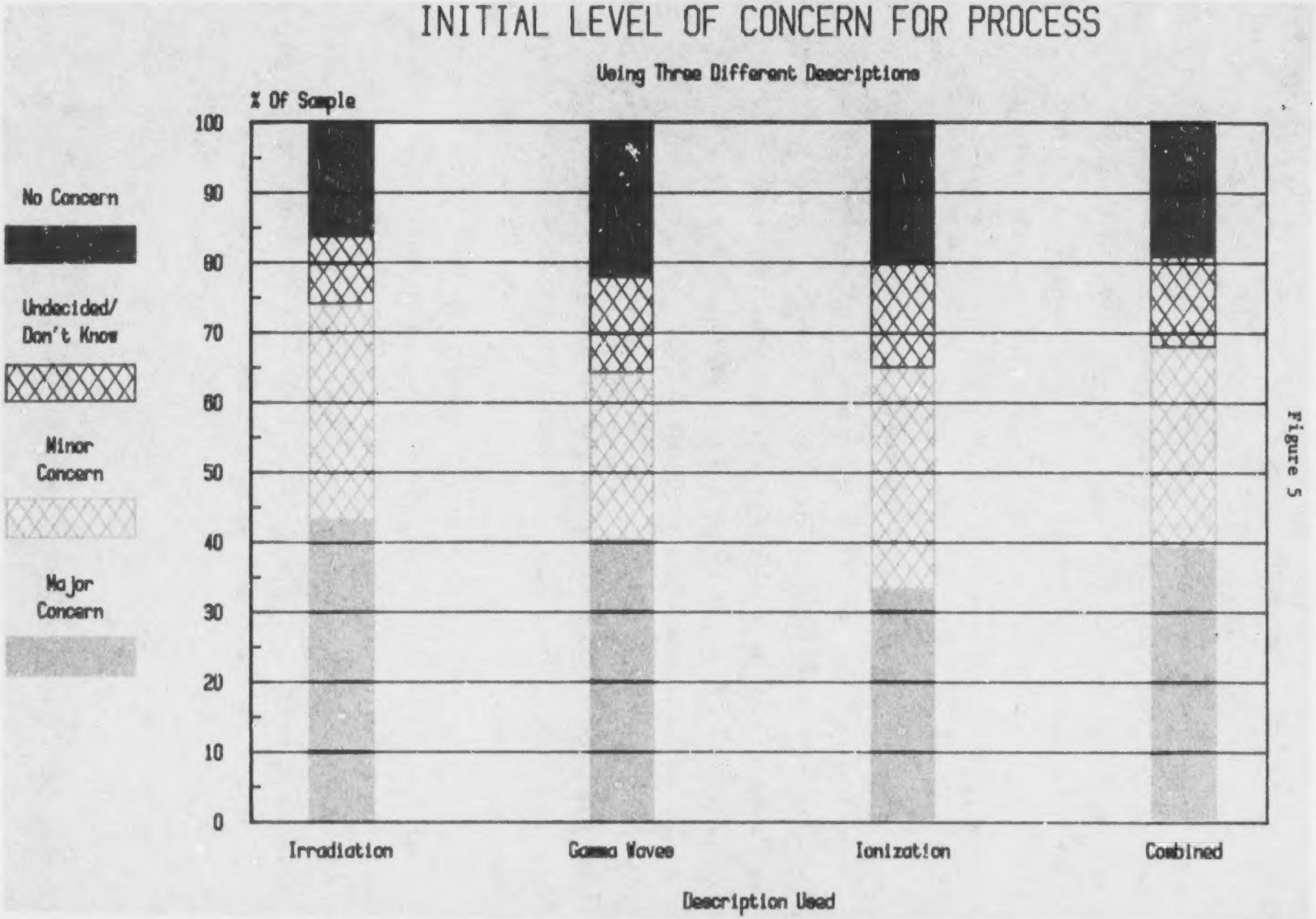
Figure 4


AWARENESS OF "IRRADIATION" PROCESSING
Using Three Different Descriptions
% Of Sample Aware
40
35
30
25
20
15
10
5
0
Gamma Waves
Irradiation
Ionization
Combined
Description Used

The reader can see that relatively little difference in perceived level of awareness for the concept was found regardless of the terminology utilized to describe the concept. In total, from about one out of every four to five adults in this country stated that they had at least heard of this method of sterilizing and preserving foods. While the majority of consumers in this country are totally unaware of the irradiation processing concept, regardless of the terminology used to describe it, assuming that awareness is non-existent or close to non-existent for the concept would be a major error. It is interesting to note that a number of consumers voluntarily mentioned very recent articles or broadcast pieces concerning this process as their source of awareness. As the information flow concerning this process increases, one would expect the awareness levels to rise and it is reasonable to hypothesize that significant gains in awareness levels for the concept have occurred, even as recently as within the past few months because of significant publicity.

Concern levels for the process of irradiation have been graphically presented in Figure 5 using the three different definitions for the process provided to consumers. These reactions do seem to suggest a lower level of concern when the ionization definition - "a technique called ionization where foods are treated with low levels of electromagnetic energy" - is used. A higher level of concern, relatively speaking, was found for the irradiation definition. When all three definitions are combined, slightly less than four out of ten consumers felt that their initial reaction to this concept would be one of major concern. Obviously, a brief initial presentation of the irradiation concept, by whatever name, holds a significant potential for generating concern among consumers.

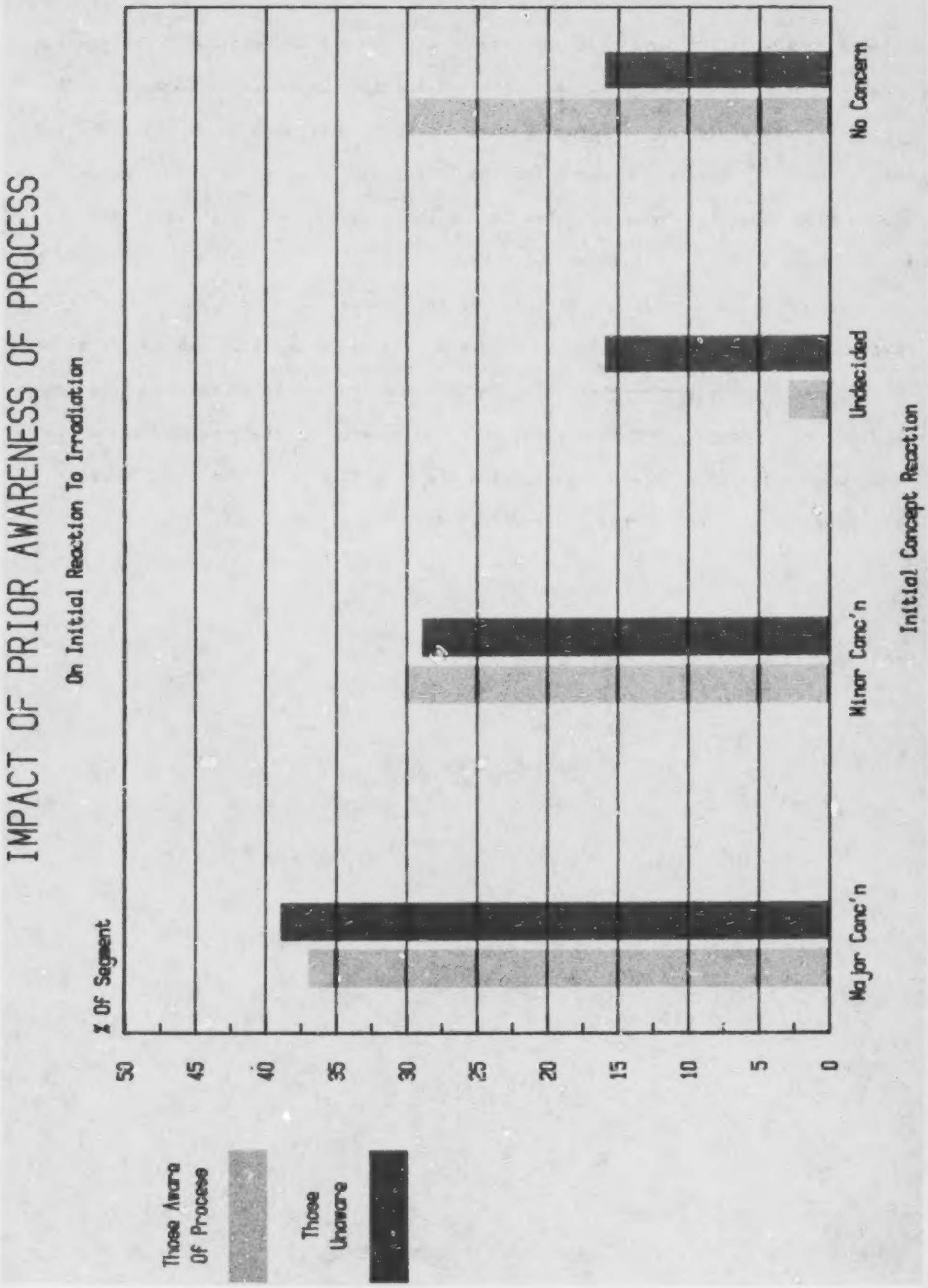
Figure 5


INITIAL LEVEL OF CONCERN FOR PROCESS
Using Three Different Descriptions
% Of Sample
100
90
80
70
60
50
40
30
20
10
0
Irradiation
Gamma Waves
Ionization
Combined
Description Used
No Concern
Undecided/ Don't Know
Minor Concern
Major Concern

A review of the levels of concern for the process by demographic categories suggests that women have a higher degree of initial concern than do men and that younger individuals carry a greater level of concern than do those over the age of fifty-five. Further, concern for the irradiation concept is lowest among those with a post-graduate education and highest among those with less than a high school degree or a high school diploma.

Given that a significant minority of the consumers in this country indicated awareness of the concept (refer to Figure 4, page 26), analysis was completed to determine if awareness to this point in time had any impact on the level of initial concern. Figure 6 demonstrates that those aware of the process have similar concern levels to those unaware with the exception of differences in the incidence of response at the "no concern" and "undecided" levels.

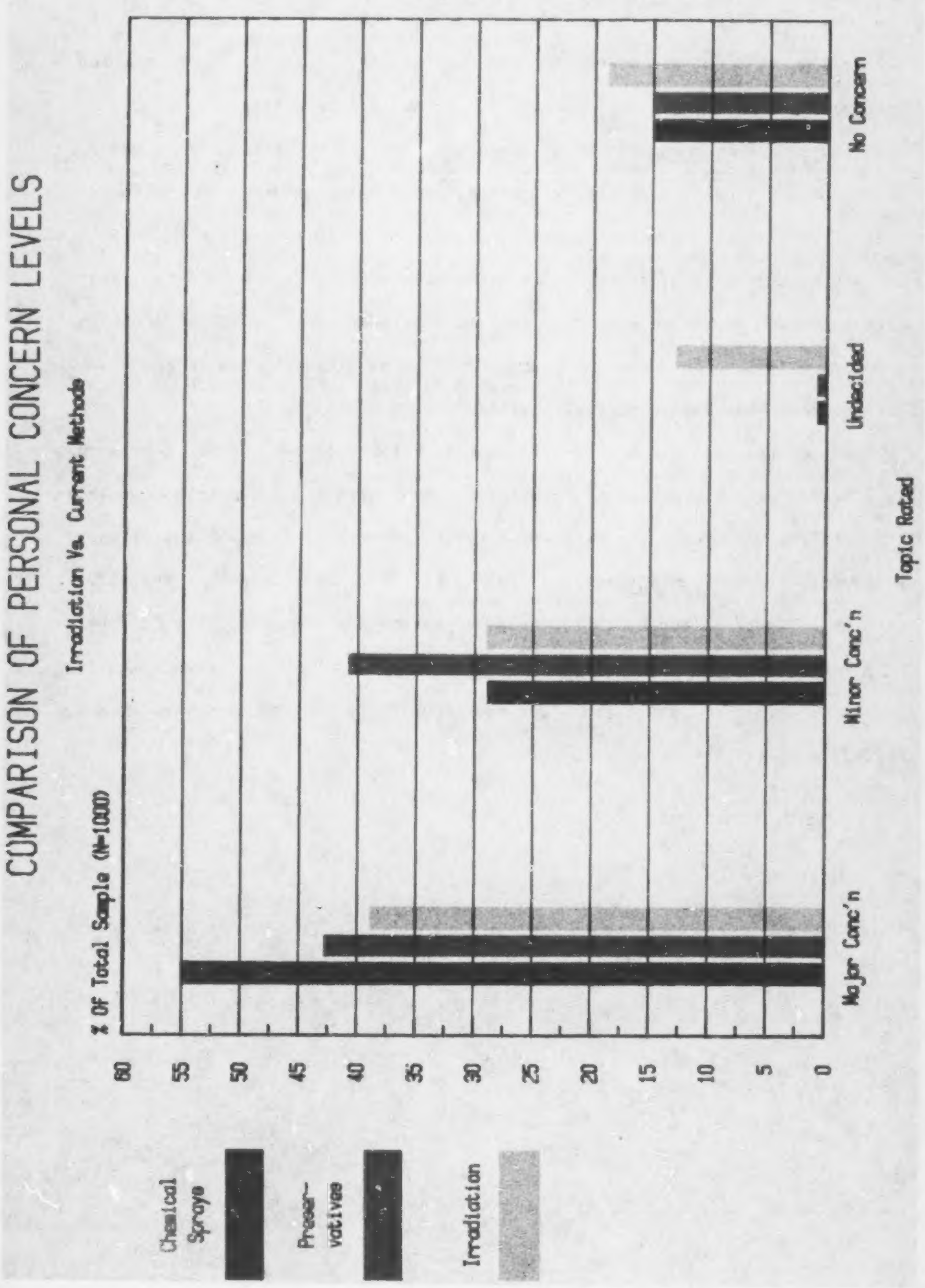
Figure 6


IMPACT OF PRIOR AWARENESS OF PROCESS
On Initial Reaction To Irradiation
% Of Segment
50
45
40
35
30
25
20
15
10
5
0
Major Conc'n
Minor Conc'n
Undecided
No Concern
Initial Concept Reaction
Those Aware Of Process
Those Unaware

People who indicated awareness of the concept were less often undecided than those unaware of the concept prior to the interview and conversely were more often found to hold no concern for the process. Apparently, information received by consumers to this point has had some positive effect by moving some indecision to a feeling of no concern. However, the incidence of major or minor concern about the process was almost identical regardless of awareness which suggests that the type or amount of information disseminated to this point has not been greatly effective in reducing high concern levels held by a significant portion of the population. Such indications might imply that additional and more effective consumer information will be necessary to reduce the significant concern that exists presently within the population.

In the previous section of this Summary Report, concern levels for current food preservation treatment techniques were presented and a comparison of these concern levels for existing techniques to the concept of irradiation, by whatever name, provides an extremely useful context for understanding these alternatives. Figure 7, on the following page, charts the concern levels for the existing treatment alternatives of chemical sprays and preservatives as well as the initial concern levels found for the irradiation concept using the combined definition alternatives.

Figure 7


COMPARISON OF PERSONAL CONCERN LEVELS
Irradiation Vs. Current Methods
% Of Total Sample (N=1000)
60
55
50
45
40
35
30
25
20
15
10
5
0
Major Conc'n
Minor Conc'n
Undecided
No Concern
Topic Rated
Chemical Sprays
Preser-vatives
Irradiation

While it is certainly true that concern exists for the irradiation concept, it is critically important to understand that the level of concern for this concept is lower than for either chemical sprays or preservatives. While fifty-five percent (55%) of the total sample expressed a major concern about chemical sprays, only thirty-eight percent (38%) expressed this level of concern for the irradiation concept. When major and minor concern levels are summed, irradiation is clearly at a lower concern level presently than either of the two existing treatment alternatives tested.

Further analysis of Figure 7 suggests a far higher segment of the consumer population which is undecided in their reaction to the irradiation concept when compared to existing treatment alternatives. The need for continued education about irradiation is supported by the fact that less than one out of five consumers in this study held no concern for the irradiation process upon initial presentation.

To effectively educate consumers and minimize the concerns for the irradiation concept, it is important to understand any perceived advantages that exist in the minds of consumers for this concept and especially understand what initial concerns consumers hold. By understanding these pluses and minuses, messages can be developed to effectively deal with specific fears or questions held by consumers and advantages can be capitalized upon. To provide this type of information, each respondent in this study was asked first what advantages they might feel exist for this type of process (irradiation) and secondly, what concerns they may have about the process. Responses to these two questions were recorded verbatim as volunteered by the respondent and later categorized for analysis purposes. Table 3 summarizes first the volunteered advantages received by consumers after their initial exposure to the concept.

Table 3

Volunteered Advantages Perceived
Possible For The Concept
Using Combined Descriptions

	Percent Of Total Sample Mentioning As...		
Volunteered Advantage	First Response	Second Response	Total Percent Mentioning
Eliminate, reduce use of chemicals:	10%	1%	11%
Eliminate, reduce use of preservatives:	2%	1%	3%
Eliminate, reduce use of additives, agents:	1%	—	1%
Less danger/chance of disease or sickness from food:	11%	2%	13%
Safer (general):	3%	1%	4%
Healthier (general):	2%	1%	3%
Preserve food longer, longer shelf life, wouldn't spoil:	6%	2%	8%
If process tested/proven safe or effective:	4%	1%	5%
Have heard process good, better:	2%	1%	3%
Lower cost, more economical:	1%	2%	3%
Method without risk of cancer:	1%	1%	2%
Feed hungry people:	1%	—	1%
All other advantages:	3%	—	3%
Don't know:	43%	—	
Nothing, none:	10%	87%	
Totals (N=1,000):	100%	100%	

A review of Table 3 shows that one of the most frequently volunteered advantages for the concept was the elimination or reduction of the use of chemicals, preservatives, or additives for food processing. Also, a fair number of perceived advantages related to reducing the danger of contracting disease or sickness from food. Some respondents also mentioned the advantage of reducing spoilage or providing longer shelf life and a few mentioned general "safer" or "healthier" perceived advantages. Relatively few individuals mentioned perceived cost benefits or helping to abate the hunger problem.

It is interesting that in total over half of the respondents to this study, after initial presentation of the concept, were unable to identify any specific advantage that they might perceive for the process. Apparently, education as to the positives of the concept will be necessary, and it is helpful to know that those consumers perceiving advantages most often see elimination or reduction of chemicals or preservatives or a reduction in the risk of disease to be pluses.

From the other direction, specific concerns volunteered for the concept after initial presentation are presented in Table 4. These concerns are extremely important to understand if effective communication efforts are to be developed to increase favorable reaction to the irradiation concept.

Table 4

Volunteered Initial Concerns For The Concept Using Three Different Descriptions

	- - - - Description Of Concept - - - -			
Volunteered Concern	Gamma Waves (N=336)	Irradiation (N=346)	Ionization (N=318)	Combined-All Descriptions (N=1,000)
Might be harmful to people (general):	7%	11%	7%	8%
Possible "side effects":	7%	5%	8%	7%
Long-term effects on people:	5%	3%	3%	4%
Radiation - if left in food, the amount, the word:	16%	24%	8%	17%
Amount of testing done, if proven:	9%	9%	9%	9%
Effect on the food:	9%	5%	9%	8%
Possible cancer-causing:	4%	8%	4%	6%
Not natural, we grow own food:	2%	2%	4%	3%
Cost efficiency, cost:	2%	2%	—	1%
How long effective, shelf life:	1%	1%	2%	1%
New, need to know more about it:	9%	6%	9%	8%
All other concerns:	1%	1%	2%	1%
Don't know:	29%	26%	38%	31%
Nothing, none:	13%	13%	10%	12%
Totals:	114%	116%	113%	116%

Percentages total to more than 100% due to multiple replies. Fifteen percent (15%) of the total sample gave more than one concern.

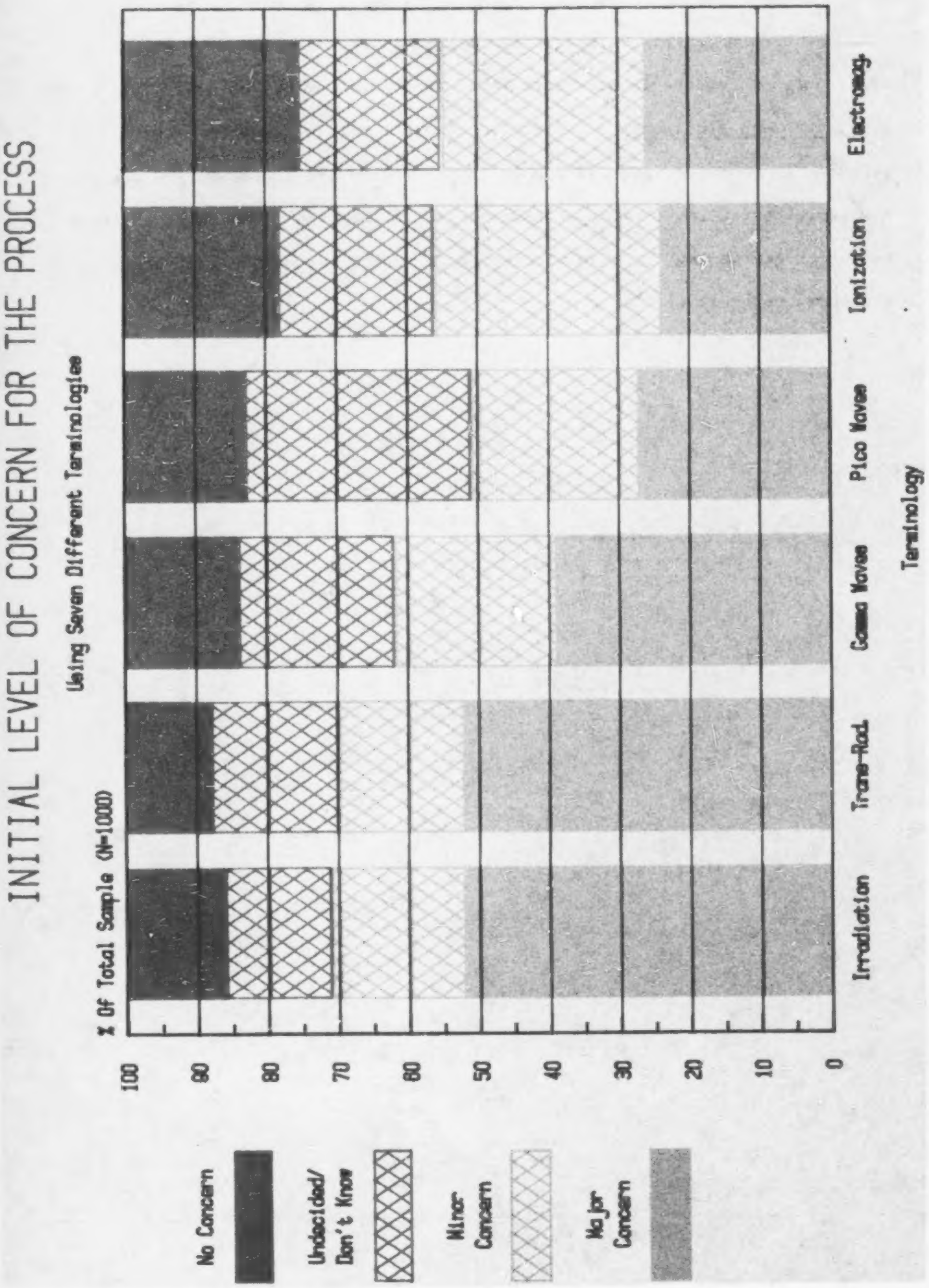
Specific categories of concern have been presented in this preceding table for each of the definition options utilized in this study as well as on a combined basis. It is interesting to note that most of the concerns were volunteered with fairly consistent frequency regardless of the initial description employed although concern about radiation, either the word, the amount, or concern about radiation being left in the food, was far more prevalent when the irradiation and gamma wave descriptions were used than when the ionization definition was given. Apparently, the direct association of ionization energy with radiation is not nearly as strong as when gamma waves or irradiation terminology is used. Still, regardless of the definition initially provided, concerns about potential harm to people, side effects, long-term effects, or radiation were mentioned frequently.

A number of people were also concerned about the amount of testing done or the fact they feel that they need to know more about this process and as questions these issues are important. A significant number of people also were concerned about the effect on the food itself (i.e., taste, nutrition, etc.). Finally, it is interesting to note the concern about the possible cancer causing characteristics of this process, even though it is not extremely large.

Overall, from about four to five out of ten respondents in this study were unable to identify any specific concern that they would have, but those who did have a concern most often held concerns that fell into the category of potential harm to people, radiation, the effect on the food, or a desire for additional information and specifically knowlege of the amount of testing done to prove the safety and effectiveness of the process. By focusing the development of effective communication messages around these concerns, sponsors of such efforts would be addressing their campaigns to the most frequently voiced concerns for the irradiation concept.

Finally, it has been noted several times that terminology used to label or describe the process seems to have an impact on consumer reaction. Ionization created somewhat less initial concern than did either irradiation or gamma wave terminology (refer to Figure 5, page 28). To provide more information about different terminologies, each respondent was presented with six different ways of labeling or naming the process and concern levels for each of these labels alone were obtained. Figure 8 summarizes these top of mind reactions for the total sample.

Figure 8


INITIAL LEVEL OF CONCERN FOR THE PROCESS
Using Seven Different Terminologies
% Of Total Sample (N=1000)
100
90
80
70
60
50
40
30
20
10
0
Irradiation
Trans-Rad.
Gamma Waves
Pico Waves
Ionization
Electromag.
Terminology
No Concern
Undecided/ Don't Know
Minor Concern
Major Concern

The terminologies of irradiation or trans-radiation received the highest concern levels of the labels tested. At the other end of the scale, ionization or electromagnetic energy received the lowest levels of concern. These differences in consumer reaction are quite pronounced and one could project that almost twice the level of major concern exists when the irradiation or transradiation terminology is used when compared to the use of the ionization or electromagnetic labels.

Section IV — The Impact Of Selected Process Attributes On Consumer Reaction To The Irradiation Concept

Consumer reactions discussed to this point in the report have been based on a very brief initial description of the irradiation process. During these questioning series, no attempts were made to provide consumers with any detailed information about the process or any potential attributes that irradiation may hold versus other methods of processing food. After initial reactions from consumers were obtained, the respondents were presented with a series of facts about the process and a series of potential benefits for irradiation. These factors were evaluated to determine the impact on consumer attitudes that each would have in either reducing or eliminating concerns about the process or the impact they would have as perceived advantages in favor of irradiation processing for food.

Analysis discussed in the following pages of this section provides extremely important information to guide the development of an education plan concerning the irradiation process. The relative ability of specific attributes to positively impact consumer attitudes should greatly assist in defining and prioritizing messages which will have the greatest opportunity for influencing consumer thought. Given that any communication or education effort is limited in resources, it only makes sense to concentrate those resources on the messages which will likely attain the greatest positive influence with the greatest number of people.

The first series of statements about the process considered by respondents related to either the use of the process or facts about irradiation. Each respondent was presented with eight such statements and asked if each would totally eliminate any concerns they may have about the process, reduce any concerns they may have a lot, reduce concerns a little, or not affect concerns they may have for the process. Figure 9 presents the results obtained both for the total sample and for that portion of the total sample who held major concerns when initially presented with the irradiation concept. For reference purposes, the labels for each of the statements used on the graph have been fully defined below as actually read to those interviewed.

Figure 9 Label Key

No Chemicals: The process leaves no chemical residue in the food.

No Radiation: The process leaves no radiation in the food.

Immunity: The process is used in the U.S. now for food consumed by people with critical immunity problems who can't tolerate any disease-causing organisms in their food.

Med. Products: The process is already used in the U.S. to sterilize about 30% of all medical and surgical products used by American hospitals.

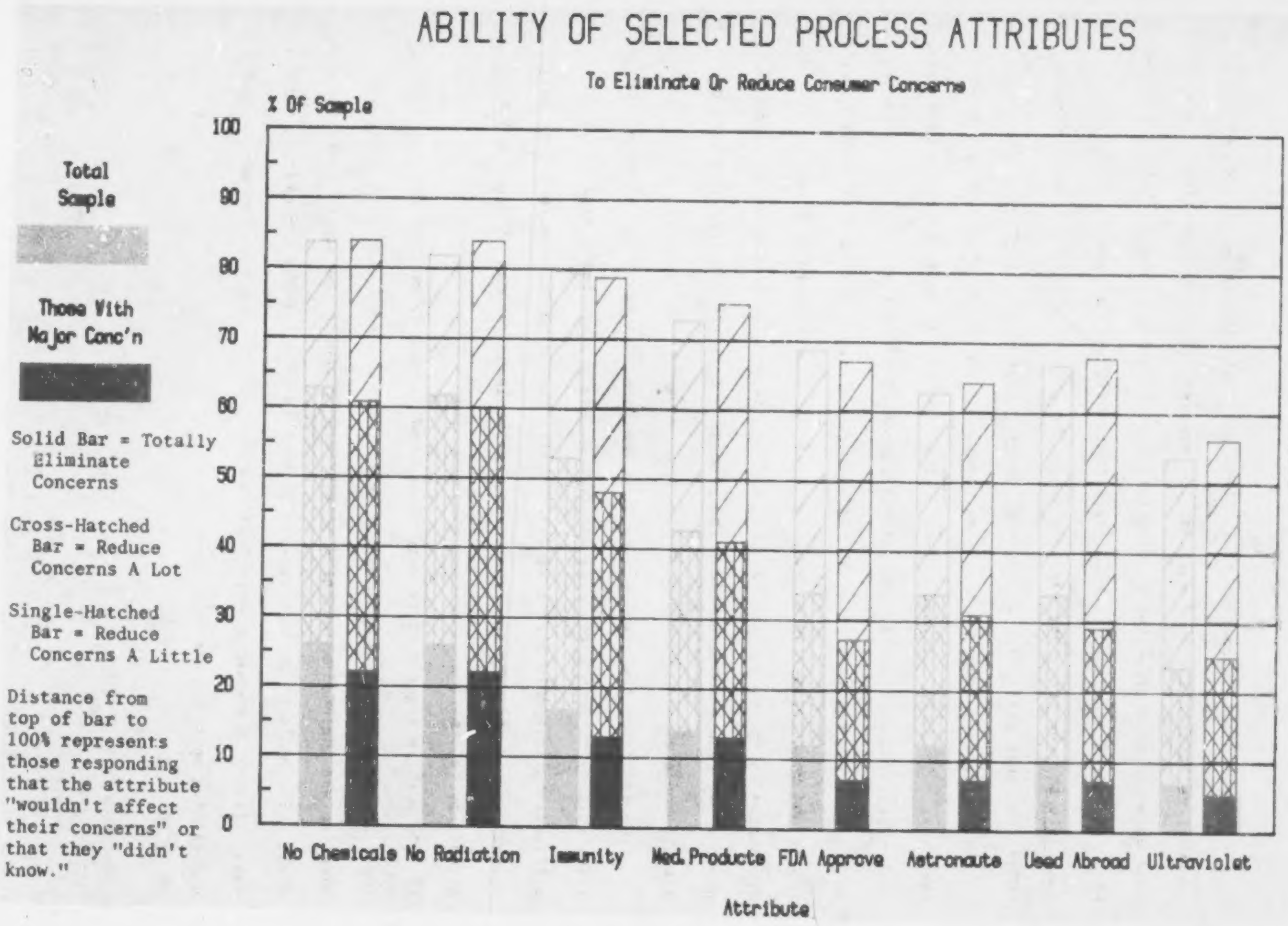
FDA Approve: The U.S. Food & Drug Administration has already approved such processing for condiments and has proposed allowing such processing for fruits and vegetables.

Astronauts: Food processed by this method has been eaten by our astronauts in space.

Used Abroad: The process has been used for some years without any apparent harm in such countries as Belgium, The Netherlands, Japan, and the Soviet Union.

Ultraviolet: The energy used for this process is similar to ultraviolet light only more powerful.

Figure 9


ABILITY OF SELECTED PROCESS ATTRIBUTES
To Eliminate Or Reduce Consumer Concerns
% Of Sample
100
90
80
70
60
50
40
30
20
10
0
Total Sample
Those With Major Conc'n
Solid Bar = Totally Eliminate Concerns
Cross-Hatched Bar = Reduce Concerns A Lot
Single-Hatched Bar = Reduce Concerns A Little
Distance from top of bar to 100% represents those responding that the attribute "wouldn't affect their concerns" or that they "didn't know."
No Chemicals
No Radiation
Immunity
Med. Products
FDA Approve
Astronauts
Used Abroad
Ultraviolet
Attribute

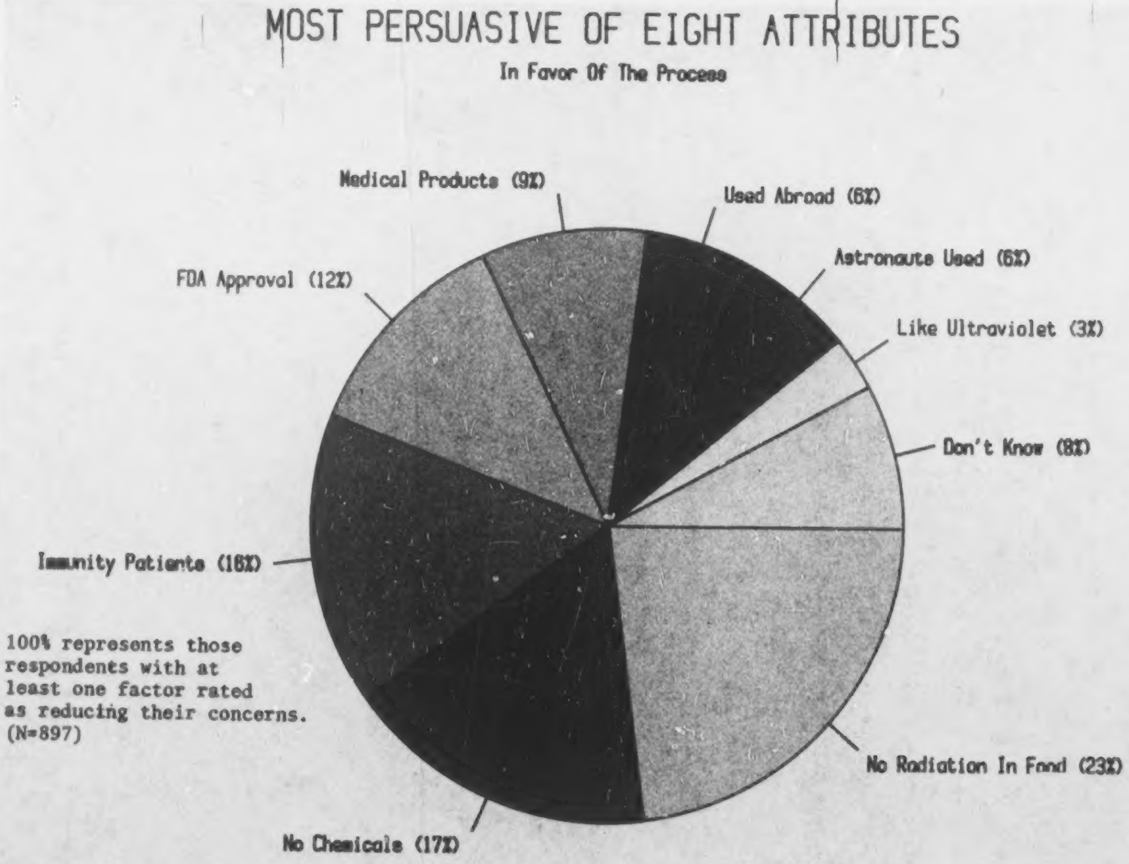
Of these eight characteristics, the facts that irradiation leaves no chemical residue in the food and that the process leaves no radiation in the food were the most effective in eliminating or reducing concerns. About one out of every four respondents in total felt that these two factors would totally eliminate any concerns they may have about the process while over sixty percent (60%) felt that these factors would at least reduce their concerns a lot.

Other factors tested were not as powerful as these in eliminating concerns, but those related to the present use of the process for foods consumed by people with critical immunity problems, sterilization of medical and surgical products in the U.S. through this process, FDA proposed approval for this processing for fruits and vegetables, the consumption of foods processed in this manner by our astronauts in space, and the historic use of the process abroad were all found to at least reduce concerns about the process a lot with one-third or more of all respondents.

The factor of the eight tested with the least favorable influence or the least ability to reduce concerns was that of the process being similar to ultraviolet light only more powerful. Still, even with this factor, over half of the respondents felt that their concerns would be reduced at least a little given this information.

Once these eight factors were considered by each respondent and rated in terms of their impact on eliminating or reducing concerns, a forced choice question was included which asked respondents to choose the single factor of the eight which would be most persuasive to them in favor of the irradiation process. Figure 10 summarizes the total sample results when this forced choice questioning approach was completed.

Figure 10



100% represents those
respondentes with at
least one factor rated
as reducing their concerns.
(N=897)

The ability of the process to leave no radiation in the food and its ability to leave no chemical residue in food were the two of the eight factors most frequently chosen as the most persuasive arguments in favor of irradiating food. Also rated fairly high was the present use of this process for foods consumed by critical immunity patients. Combined, these three factors accounted for over half of the choices of all respondents as the most persuasive of the eight factors. Therefore, these characteristics probably deserve emphasis in any communication plan. Still, the other factors all seemed to possess the ability to reduce concerns to a significant degree and therefore none would need to be totally neglected.

A second series of attributes was also presented to respondents, and these characteristics could more aptly be referred to as potential benefits of the process. For each of these benefits, the respondent was asked to make a rating based on whether they would see it as either a major advantage for the process, a minor advantage, or no perceived advantage in favor of the irradiation process. Figure 11 summarizes the degree of perceived advantage for each of these ten additional attributes and the labels for each attribute as shown on the graph can be correlated with the complete description provided to respondents as shown on the following page.

Figure 11 Label Key

World Hunger: The process could help ease the world hunger problem since today many countries lose 30% or more of their food production to spoilage and insects prior to consumption.

Chemicals: Would reduce or eliminate the need to use chemicals on fruits and vegetables.

Spoilage: Would greatly reduce the spoilage losses of foods.

Cost: Would lower the cost of foods by eliminating the need for freezing and continued refrigeration.

Preserve: The process would reduce or eliminate the need for preservatives such as nitrites in the foods processed.

Nutrition: There is almost no change in color, texture, or nutritious qualities of foods with this technique.

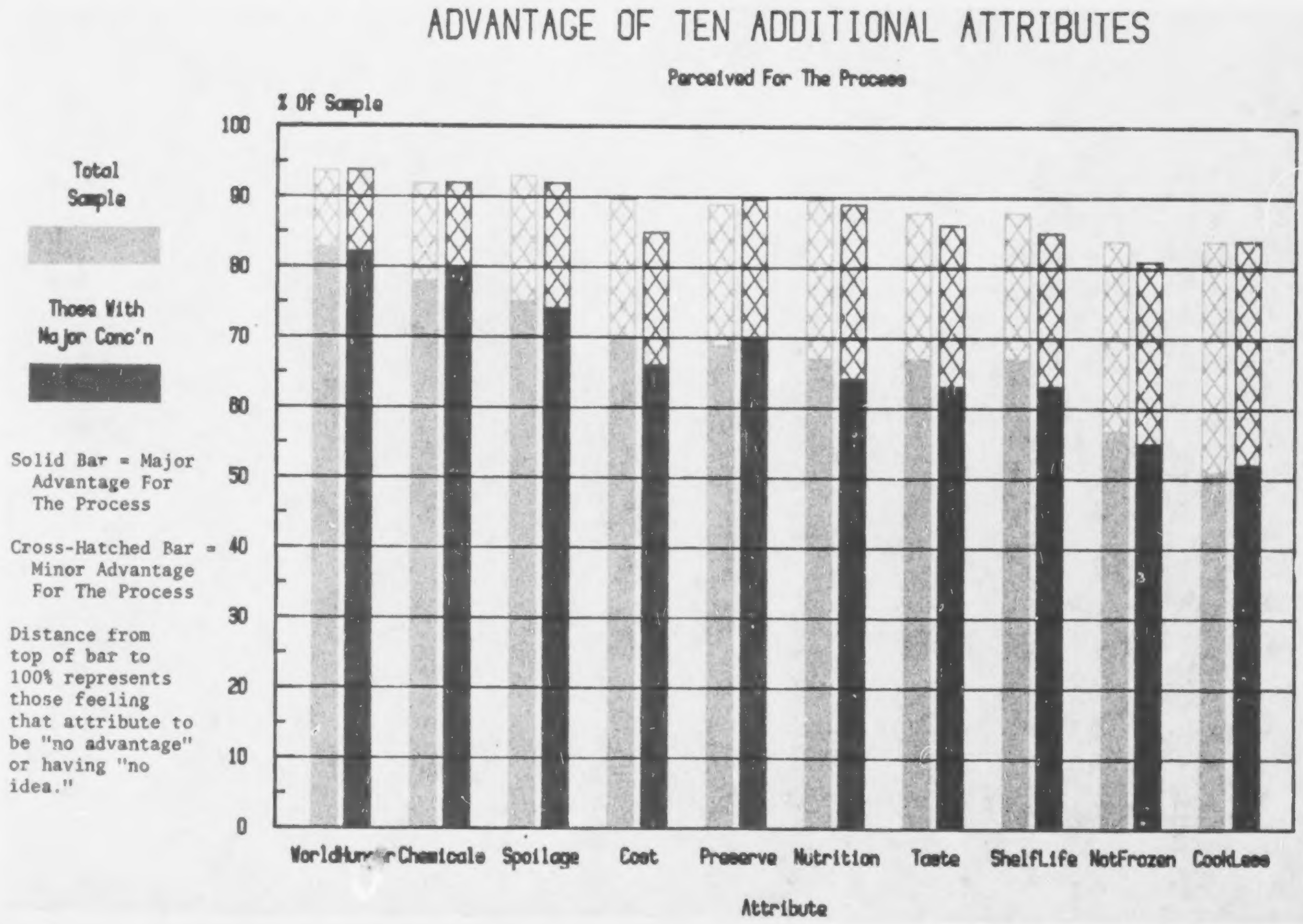
Taste: The technique doesn't noticeably change the taste of foods.

Shelf Life: Would extend the shelf life for certain foods or the time the food would remain unspoiled from several days to several weeks.

Not Frozen: Would allow items processed in specialized areas of the country, such as fish, fruits, and vegetables, to be shipped chilled but not frozen to other areas.

Cook Less: Would allow you to cook foods for shorter periods.

Figure 11


ADVANTAGE OF TEN ADDITIONAL ATTRIBUTES
Perceived For The Process
% Of Sample
Total Sample
Those With Major Conc'n
Solid Bar = Major Advantage For The Process
Cross-Hatched Bar = Minor Advantage For The Process
Distance from top of bar to 100% represents those feeling that attribute to be "no advantage" or having "no idea."
100
90
80
70
60
50
40
30
20
10
0
WorldHunger
Chemicals
Spoilage
Cost
Preserve
Nutrition
Taste
ShelfLife
NotFrozen
CookLess
Attribute

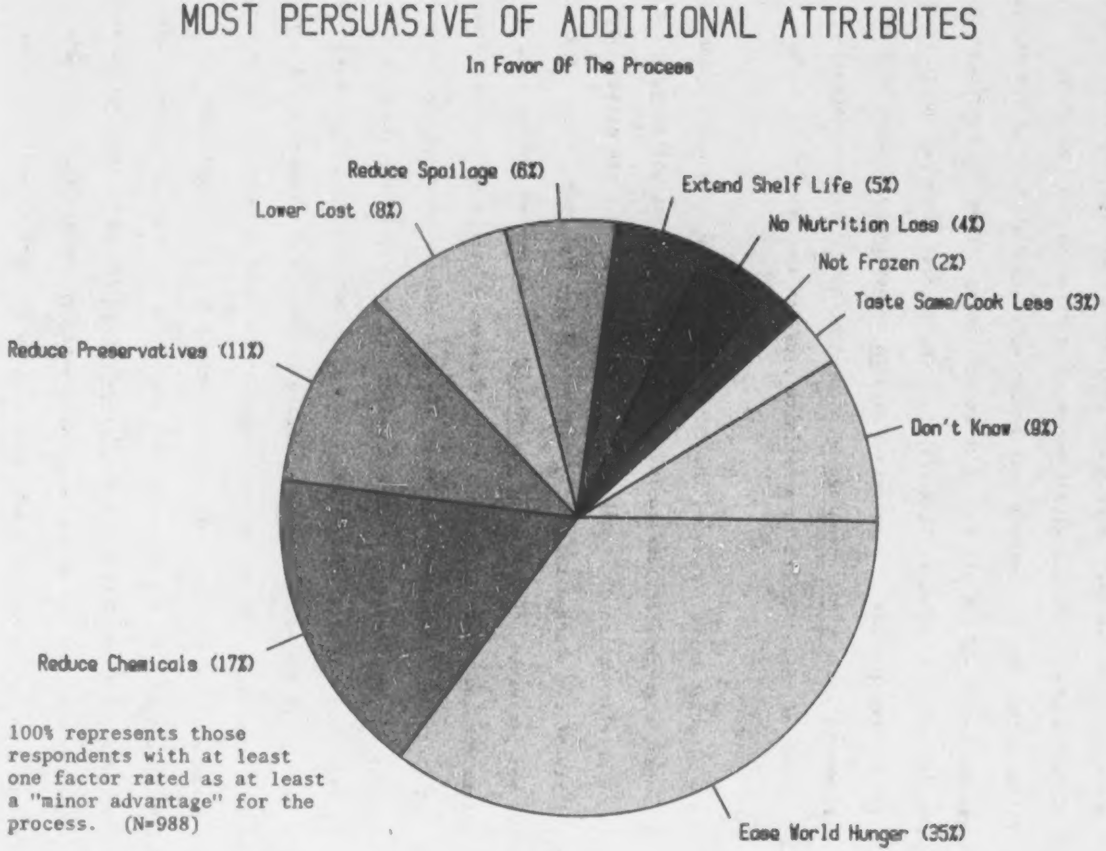
Again, this figure shows the perceived advantages for each of the attributes first among those in the total sample and then among those who initially expressed a major concern when presented with the concept earlier in the interview.

Probably the most predominant pattern reflected in Figure 11 is the strength of advantage perceived for all ten of these attributes. Even the attribute rated at the relatively lowest level, that of the process allowing one to cook foods for shorter periods, was perceived as a major advantage by over half of all respondents and a minor advantage by over eight out of ten respondents. Clearly, each of these factors is a definite plus for the process in the minds of most consumers.

On a relative basis, however, the three most powerful advantages appear to be the impact that this process could have on helping to ease world hunger, the reduction or elimination of chemicals for fruit and vegetable processing, and the ability of the process to greatly reduce spoilage for foods. Each of these factors was perceived to be a major advantage by three out of four or more of all respondents and therefore each obviously deserves strong consideration in any communication efforts. In addition, the cost effectiveness of the process, the ability of the process to reduce or eliminate preservatives, the fact that the process does not alter the color, texture, or nutritional qualities of the food, as well as issues related to no change in taste and extended shelf life were also perceived to be strong advantages by the vast majority of respondents.

Because of the positive influence of each of these ten variables, the results in the next figure can help sort priorities for communication or education efforts. Figure 12 reflects the forced choice rating of the most persuasive attribute seen of the second series of ten tested in the minds of consumers. In this forced choice rating approach, several beenfits tend to solidify their position of importance.

Figure 12



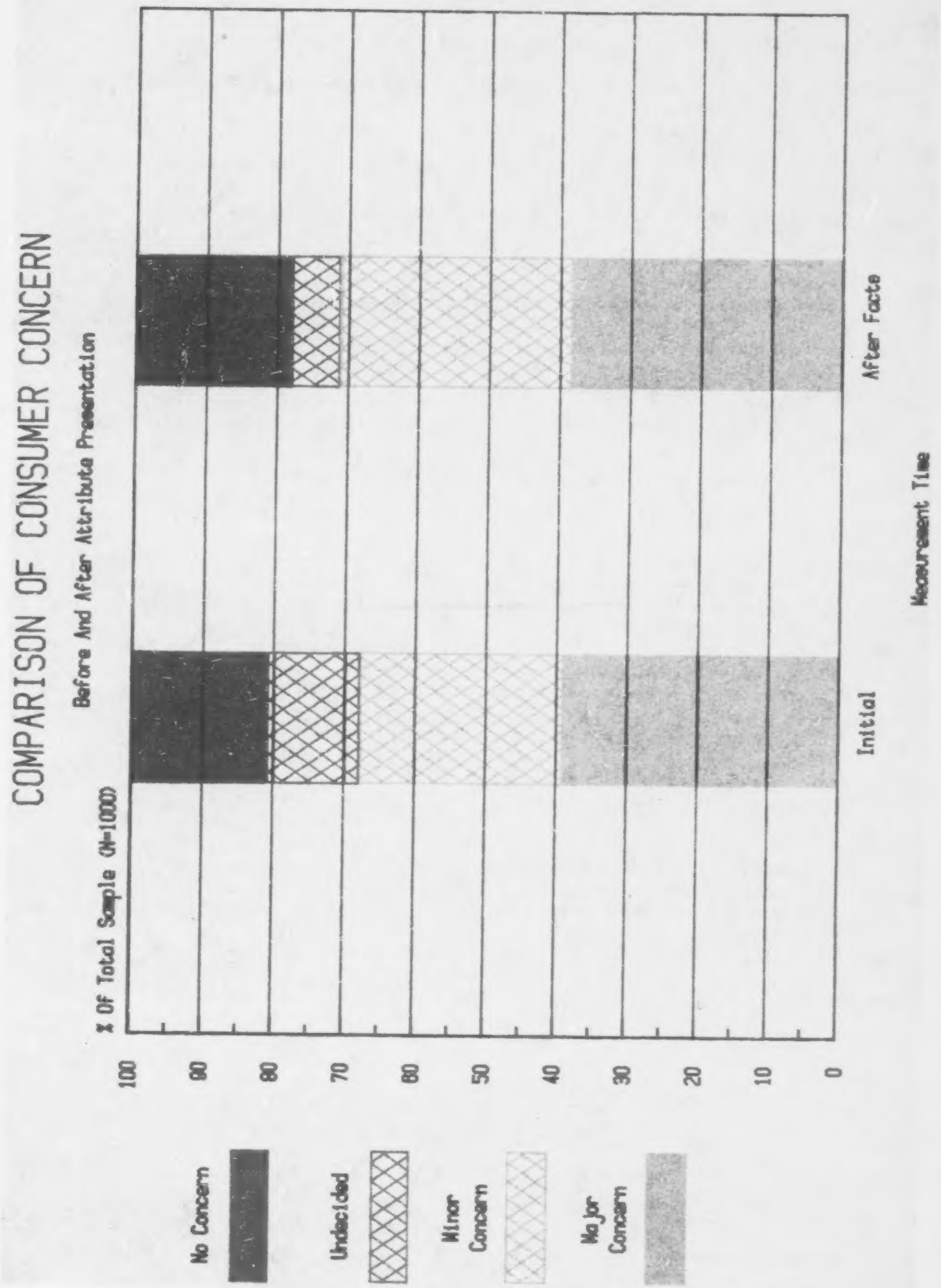
100% represents those respondents with at least one factor rated as at least a "minor advantage" for the process. (N=988)

The ability of the process to help ease world hunger was the most persuasive of the additional attributes seen by most consumers. This attribute was chosen as the most influential in favor of the process about twice as often as the next closest attribute, that of being able to reduce or eliminate the need to use chemicals on fruits and vegetables. Following these two benefits, the reduced use of preservatives was seen by eleven percent (11%) of all consumers as the most powerful or persuasive of the remaining ten attributes with all other factors being selected as the most influential attribute by less than ten percent (10%) of all respondents.

The fact that nearly two-thirds of all respondents identified either the ability of the process to help ease world hunger or to reduce or eliminate chemicals or preservatives in foods definitely brings these attributes to the top of the list when content areas are being considered for educational or communication efforts. This is not to say that the other tested attributes are not perceived as advantages, but when difficult decisions about which messages should be focused upon are made, these priorities should probably be followed given their greater degree of impact on a greater number of people.

Given the ability of all eighteen characteristics or attributes of the process to either reduce concerns or to be be perceived as advantages of the process, one might think that consumers, after exposure to all of these attributes, would hold greatly reduced concerns about the process versus those concerns expressed after a brief initial description. However, the results in Figure 13 which depict the level of concern for the process, both initially and after all attributes had been presented, dispel this notion.

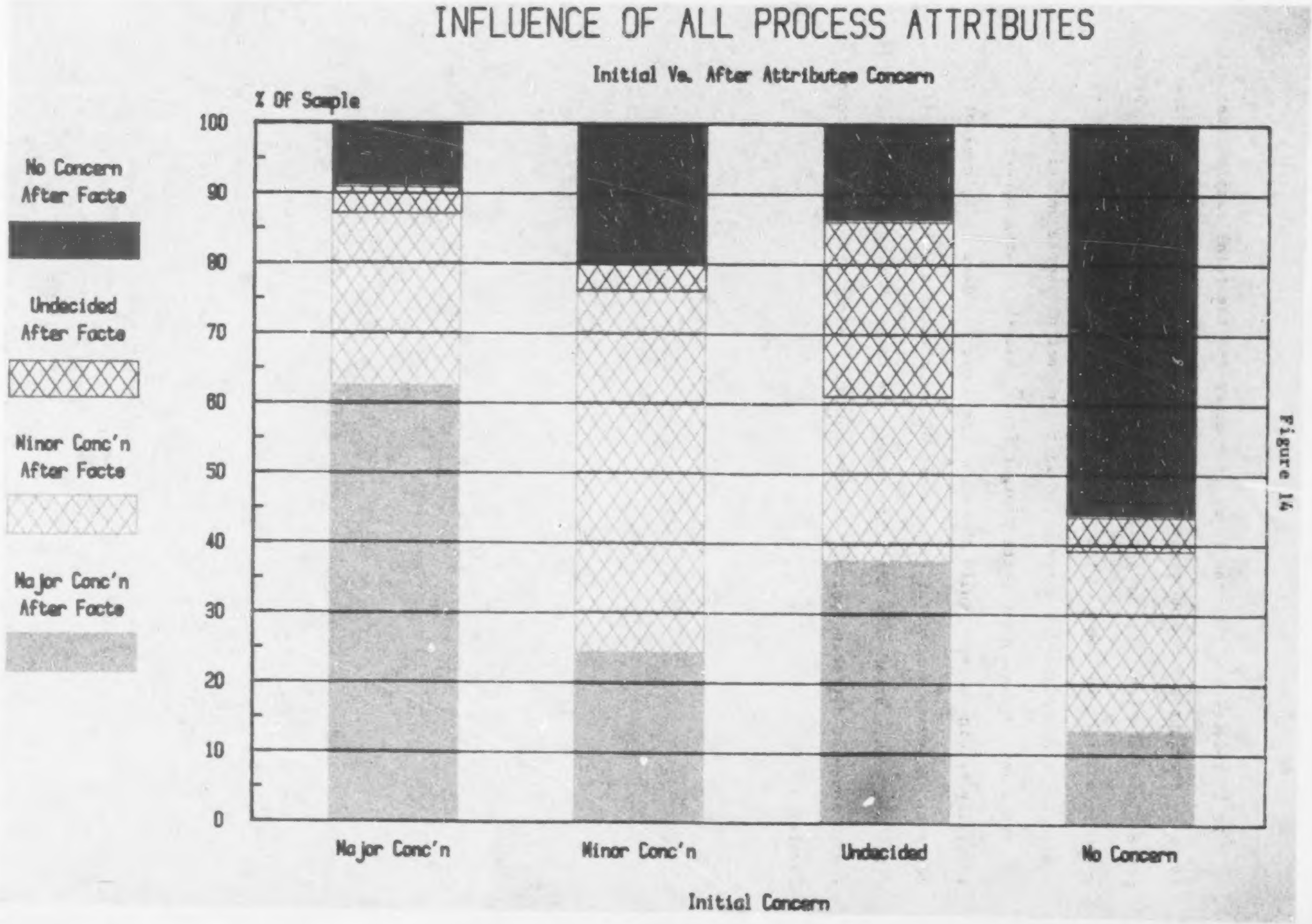
Figure 13


COMPARISON OF CONSUMER CONCERN
Before And After Attribute Presentation
% Of Total Sample (N=1000)
100
90
80
70
60
50
40
30
20
10
0
Initial
After Facts
Measurement Time
No Concern
Undecided
Minor Concern
Major Concern

It is interesting that the level of concern for the total sample after all facts or attributes had been presented was essentially the same as after initial process presentation. The only significant change after attribute presentation would be a slight increase in the number of people who hold no concern whatsoever for the process and a reduction in the number of people undecided.

This fairly consistent pattern might imply that those with concerns initially retain concerns while those who are undecided move to a level of no concern. However, more detailed analysis of the attitudes before and after attribute presentation show that this is not the case. The results in Figure 14 show a somewhat different pattern of movement for "before and after" concern levels.

Figure 14


INFLUENCE OF ALL PROCESS ATTRIBUTES
Initial Vs. After Attributes Concern
% Of Sample
100
90
80
70
60
50
40
30
20
10
0
Major Conc'n
Minor Conc'n
Undecided
No Concern
Initial Concern
No Concern After Facts
Undecided After Facts
Minor Conc'n After Facts
Major Conc'n After Facts

Each of the bars in the preceding figure represents the concern level voiced by respondents initially, before any attributes of the process were specifically presented. In the first bar, those people with a major concern initially then have their attitude or concern level about the process after facts were presented represented by the various segments of that first bar. A review of that first bar clearly shows that over a third of the people with initial major concerns reduced those concerns, most often to a minor concern level, and in about thirteen percent (13%) of all cases to a level of indecision or of no concern whatsoever after attributes were presented.

Looking at those people with minor concerns initially, a majority continued to hold minor concerns but nearly one out of four developed major concerns for the process after attribute presentation. Some gains, however, were made within this group as two out of ten held no concerns after attribute presentation.

Those initially undecided about the process were found, in over a third of all cases, to have developed major concerns for the process after attribute or fact presentation. In total, over six out of ten indicated that they would have at least minor concerns after the facts were presented. This trend would imply that those undecided clearly fall more often on the concern side of the scale than on the non-concern side of the scale after all eighteen attributes are considered.

Finally, those people initially expressing no concern about the process were, in a majority of cases, found to hold no concern after attribute presentation. Still, nearly four out of ten held at least a minor concern after the issues represented by the attributes were raised for their consideration.

Some interpretations or hypotheses about this apparent discrepancy of continued levels of concern after attribute presentation must be attempted. It is not possible from this research project and the questioning included in it to confidently determine the specific reason for a maintenance of concern levels in many cases or even a building of concern levels for the process after eighteen attributes, most of which consumers felt were definite positives in favor of the process, had been provided to consumers. Several plausible explanations, any or all of which could influence this phenomenon would be:

1- Discussion of the attributes raised issues to consumers that they had not initially considered when presented with the process the first time.

2- A number of the respondents may not have accepted the attributes as necessarily being fact when presented through an interview format such as that used in this study.

3- Although the nature of specific concerns about the process may well have been altered through the attribute presentation series, lingering concerns or concerns of a different nature may have taken the place of initial concerns.

Certainly other possible explanations deserve consideration for this apparent discrepancy in logic. However, it is clear that simple presentation of the attributes discussed in this research project is not likely going to eliminate or greatly reduce the concern level on the part of most consumers. The fears of some people will be reduced while those of others might be heightened by the presentation of the types of information included here. Such a finding could be used to support the premise that educational levels would not be worthwhile expenditures of resources and that the likely result of such expenditures would be concern levels equal to those without such education. However, it is more likely that the attributes themselves are not the ineffectual part of the presentation here and that the interview process could be expected to be far less persuasive as an educational or informational technique than ones that could be developed by professionals who can clearly and convincingly communicate such information through more acceptable media.

The probable ability of subsequent educational efforts to influence consumers is supported when the remaining concerns voiced by consumers after all attributes had been presented are reviewed. Table 5 on the following page summarizes these concerns and the nature of these fears appears to be altered somewhat from those voiced after the process was initially presented.

Table 5

Volunteered Concerns For The Process Remaining After Attributes Presented

	Percent Of Those With A Major Or Minor Concern (N=713).		
Volunteered Concern	First Response	Second Response	Total Percent Mentioning
Amount of testing done, if proven:	21%	5%	26%
New, need to know more about it:	22%	2%	24%
Might be harmful to people (general):	9%	3%	12%
Possible "side effects":	3%	3%	6%
Long-term effects on people:	5%	2%	7%
Radiation - if left in food, the amount, the word:	9%	2%	11%
Effect on the food:	7%	3%	10%
Not natural, we grow own food:	4%	2%	6%
Possible cancer-causing:	3%	2%	5%
How long effective, shelf life:	2%	1%	3%
Cost efficiency, cost:	2%	1%	3%
All other concerns:	4%	1%	5%
Don't know:	7%	—	
Nothing, none:	2%	—	
No Second Response:	—	73%	
Totals:	100%	100%	

The importance of communicating the amount of testing done for the irradiation process becomes evident when Table 5 is reviewed. Many consumers are interested in the amount of testing historically done and the degree to which the process has been proven safe or effective. Further, a similar number of respondents stated the belief that this process was new and that they would need to know more about it before their concerns could be eliminated. Such findings would suggest that these people had not totally accepted the information presented in the interview as necessarily factual.

Certainly there are those who continue to have concerns about the long-term effects of the process and the possibility of the process being harmful to people. Further, a fair number also remained concerned about radiation itself and others about the subsequent effect of the process on the food.

In summary, a simple presentation of attributes to consumers, at least in an interview format, will not apparently eliminate or even dramatically reduce their concern levels about the irradiation process on balance. However, carefully structured and convincing educational efforts concentrating on some of the attributes with the greatest demonstrated ability to influence people will likely have some positive effect. The concerns that seem to remain after initial education, however, will obviously need strong emphasis and these suggest primarily a clear presentation of the amount of testing done to prove the effectiveness and safety of the process and information to eliminate concerns about the potential of the process to cause harmful effects from a health standpoint. The issue of radiation must be dealt with effectively as well as the minimal effect of the process on the food itself. By keeping these consumer concerns in mind as well as those initially voiced by consumers, NPPC, the

Department of Energy, and others interested in promoting the attributes of the irradiation process should be in a better position to effectively and efficiently deal with consumer concerns which are clearly significant but less prevalent than concerns for the existing treatment methods currently being utilized.

National Pork Producers Council
Consumer Reaction To The Irradiation Concept

Wiese Research Associates, Inc.
February 3 - 13, 1984

INTRODUCTION

Hello, my name is ________ and I'm with WRA Research, an independent opinion research firm in Omaha, Nebraska. We are conducting a nationwide survey of adults 18 or older concerning attitudes about food processing and preservation. The survey is not long - about ten minutes - and I need to talk with the person in your household 18 or older who has had their birthday most recently.

If respondent - (Continue with Q#1 at arrow.)
If other - (Ask for that person, repeat introduction, or if that person not available, obtain first name and schedule time for callback.)

ID#____________ (1)-(3)

Phone Number: (__________) ______________________
Area Code Number

Respondent's Name: ______________________________

State: ______________________________

Interviewer: ____________________/ID#__________ (4)-(5)

Validated By: ______________________________

CLASSIFICATION INFORMATION - COMPLETE AT THE END OF THE INTERVIEW

30. Are you the primary food shopper for your househld or would that be someone else? (open-ended)

(Ask Q#31)	Primary Food Shopper	1	(6)
(Skip to Q#32)	Not Primary	2	

31. Do you read labels on processed food you buy specifically to see what processes, chemicals, or preservatives have been used? (read responses)

All of the time	1	(7)
Most of the time	2	
Occasionally	3	
Or, Never	4	

32. Are you: (read responses)

18 - 24	1	(8)
25 - 34	2	
35 - 44	3	
45 - 54	4	
55 - 64	5	
65/Above	6	

33. What is the highest level of education you have had the opportunity of completing? (read responses)

Less than High School graduate	1	(9)
High School graduate	2	
Some college or formal technical training beyond high school	3	
College graduate	4	
Post graduate	5	

34. Is the city or community you live in: (read responses)

Over 500,000 population	1	(10)
From 150,000 - 500,000 population	2	
From 50,000 - 150,000 population	3	
From 10,000 - 50,000 population	4	
Under 10,000 population	5	
Or, rural (outside of any city/town)	6	

35. Including yourself, how many family members are there in your household? (open-ended)

One..............1 (11)
Two..............2
Three..............3
Four..............4
Five or Six..............5
Seven or More..............6

36. Is the total income including all wage earners in your household under or over $25,000 per year before taxes?

(If "under", ask:) Under or over $15,000?
(If "over", ask:) Under or over $40,000?

Thank Respondent & Terminate---------Under $15,000..............1 (12)
$15,000 - $24,999..............2
$25,000 - $40,000..............3
Thank Respondent & Terminate---------Over $40,000..............4

RECORD THE FOLLOWING ONLY - DO NOT ASK

37. Sex Of Respondent:

Male..............1 (13)
Female..............2

38. Process Description Used: (From Q#3)

A. (Gamma)..............1 (14)
B. (Irradiation)..............2
C. (Ionization)..............3

39. Reaction To Process Initially: (From Q#3)

Major Concern..............1 (15)
Minor Concern..............2
No Concern..............3
Undecided..............4

40. Geographic Area:

New England/Metro New York..............1 (16)
Middle Atlantic..............2
East Central/Metro Chicago..............3
West Central..............4
Southeast..............5
Southwest..............6
Pacific Coast/Metro L.A..............7

_____(17)
_____(18)
_____(19)

⇨ INTERVIEWER - START HERE AFTER INTRODUCTION & SCREENING

1. How much concern do you personally have with: (rotate A-D and read responses)

(ROTATE A-D)	Major Concern	Minor Concern	No Concern	(Undecided/ Don't Know)	
A. Preservatives that are being used in some of the foods you eat:	1	2	3	(4)	_____(20)
B. Sprays or chemicals used on some fruits and vegetables that you eat:	1	2	3	(4)	_____(21)
C. The risk of becoming ill from diseases in or carried by food that you eat:	1	2	3	(4)	_____(22)
D. The waste from having to throw away food you buy that spoils before you can eat it:	1	2	3	(4)	_____(23)

2. More specifically, do you eat less: (rotate A-H and read responses if "yes")

- - - (If "yes", ask:) - - -

(ROTATE A-H)	A Lot Less	Some Less	A Little Less	No	
A. Fresh pork than you might otherwise because of the risk of trichinosis:	1	2	3	4	______(24)
B. Processed pork such as bacon than you otherwise might because of nitrites used as preservatives:	1	2	3	4	______(25)
C. Processed pork such as ham or sausage than you otherwise might because of the salt content:	1	2	3	4	______(26)
D. Fruits than you otherwise might because of the chemicals used to treat them:	1	2	3	4	______(27)
E. Vegetables than you otherwise might because of chemicals used to treat them:	1	2	3	4	______(28)
F. Fish than you otherwise might because of the risk of disease:	1	2	3	4	______(29)
G. Poultry than you otherwise might because of the risk of disease:	1	2	3	4	______(30)
H. Beef than you otherwise might because of the risk of disease:	1	2	3	4	______(31)

3. There has been developed and refined a method for sterilizing and preserving foods that kills any harmful organisms or diseases that may be present by (insert either A, B, or C description - only one per respondent). Just given your initial reaction, would you have a major concern, a minor concern, or no concern about this process if it was to be used for foods you consume?

	Major Concern	Minor Concern	No Concern	(Undecided/ Don't Know)	
A. Treating them with gamma waves, energy like ultra-violet light but more powerful:	1	2	3	(4)	______(32)
B. A technique called irradiation where foods are treated with low levels of irradiation energy:	1	2	3	(4)	______(33)
C. A technique called ionization where foods are treated with low levels of electromagnetic energy:	1	2	3	(4)	______(34)

USE ONLY ONE PER RESPONDENT!

4. Prior to this interview, had you ever heard of this method of sterilizing and preserving foods? (open-ended)

Yes................1 (35)
No.................2
Not Sure...............3

5. What advantages do you feel might exist for this type of process? (open-ended and probe fully)

____ ______(36)

____ ______(37)

____

____

What others? ____________________________________ ______(38)

____ ______(39)

____

____

6. Turning that around, what concerns might you have about this type of process? (open-ended and probe fully)

____ ______(40)

____ ______(41)

____

____

What others? ____________________________________ ______(42)

____ ______(43)

____

____

7. Now I'm going to read a series of terms that describe ways food might be processed to preserve and sterilize it. For each term I read, please tell me if you would have a major concern, a minor concern, or no concern about having food you eat processed in this way.

> INTERVIEWER: If needed, explain to respondent that we are interested in their impression. It doesn't have to be based on any knowledge of what the process involves - only the reaction to the term.

(Rotate A-F)	Major Concern	Minor Concern	No Concern	(No Idea/ Undecided)	
A. Processed by ionization energy:	1	2	3	(4)	______(44)
B. Processed by electromagnetic energy:	1	2	3	(4)	______(45)
C. Processed by trans-radiation:	1	2	3	(4)	______(46)
D. Processed by pico (pie-co) waves:	1	2	3	(4)	______(47)
E. Processed by gamma waves:	1	2	3	(4)	______(48)
F. Processed by irradiation:	1	2	3	(4)	______(49)

8-15. The following are some arguments that have been forwarded in favor of the sterilization and preservation processing methods I've mentioned. Please consider each separately as I read through the list and tell me if that fact: (read responses)

(Rotate 8-15)	Would Totally Eliminate Any Concerns You May Have	Would Reduce Your Concerns A Lot	Would Reduce Your Concerns A Little	Wouldn't Affect Your Concerns	(No Idea)	
8. The U.S. Food & Drug Administration has already approved such processing for condiments and has proposed allowing such processing for fruits and vegetables:	1	2	3	4	(5)	____(50)
9. The process has been used for some years without any apparent harm in such countries as Belgium, The Netherlands, Japan, and the Soviet Union:	1	2	3	4	(5)	____(51)
10. The process is already used in the U.S. to sterilize about 30% of all medical and surgical products used by American hospitals:	1	2	3	4	(5)	____(52)
11. Food processed by this method has been eaten by our astronauts in space:	1	2	3	4	(5)	____(53)
12. The energy used for this process is similar to ultraviolet light only more powerful:	1	2	3	4	(5)	____(54)
13. The process is used in the U.S. now for food consumed by people with critical immunity problems who can't tolerate any disease-causing organisms in their food:	1	2	3	4	(5)	____(55)
14. The process leaves no radiation in the food:	1	2	3	4	(5)	____(56)
15. The process leaves no chemical residue in the food:	1	2	3	4	(5)	____(57)

INTERVIEWER: Complete the following question using only those issues in Q#8-15 rated as "1"s, if at least two rated at this level. If only one factor rated at this level, skip to Q#16 recording this factor as the response. If none at the "1" level, use those factors rated as "2"s.

16. Of the following factors, (re-read in total those rated as "1"s in Q#8-15), which one is the most persuasive to you in favor of the process? (re-read factors as needed)

Interviewer Summary

Q#8 - FDA Approved	1	(58)
Q#9 - Used In Other Countries	2	
Q#10 - Surgical Instruments	3	
Q#11 - Astronauts	4	
Q#12 - Ultraviolet Light	5	
Q#13 - Immunity Patients	6	
Q#14 - No Radiation In Food	7	
Q#15 - No Chemicals In Food	8	
(Don't Know/None)	(9)	

17-26. The following are some additional arguments that have been made in favor of using this technique for sterilizing and preserving foods. Please consider each separately as I read through the list and tell me if you would see that fact to be: (read responses)

(Rotate 17-26)	A Major Advantage For The Process	A Minor Advantage For The Process	Or, No Advantage For The Process	(No Idea)	
17. The process would reduce or eliminate the need for preservatives such as nitrites in the foods processed:	1	2	3	(4)	______(59)
18. Would reduce or eliminate the need to use chemicals on fruits and vegetables:	1	2	3	(4)	______(60)
19. Would extend the shelf life for certain foods or the time the food would remain unspoiled, from several days to several weeks:	1	2	3	(4)	______(61)
20. Would allow items processed in specialized areas of the country, such as fish, fruits, and vegetables, to be shipped chilled but not frozen to other areas:	1	2	3	(4)	______(62)
21. Would lower the cost of foods by eliminating the need for freezing and continued refrigeration:	1	2	3	(4)	______(63)
22. Would greatly reduce the spoilage losses of foods:	1	2	3	(4)	______(64)
23. Would allow you to cook foods for shorter periods:	1	2	3	(4)	______(65)
24. The technique doesn't noticeably change the taste of foods:	1	2	3	(4)	______(66)
25. There is almost no change in color, texture, or nutritious qualities of foods with this technique:	1	2	3	(4)	______(67)
26. This process could help ease the world hunger problem since today many countries lose 30% or more of their food production to spoilage and insects prior to consumption:	1	2	3	(4)	______(68)

INTERVIEWER: Complete the following question using only those factors in Q#17-26 rated as "1"s if at least two rated at this level. If only one factor rated at this level, skip Q#27 recording this factor as the response. If none at the "1" level, use those factors rated as "2".

27. Of the following factors, which one is the most persuasive to you in favor of the process? (Re-read in total those rated as "1"s in Q#17-26.)

Interviewer Summary

Q#17 - Reduce Preservatives	...01	(69)
Q#18 - Reduce Use Of Chemicals	...02	(70)
Q#19 - Extend Shelf Life	...03	
Q#20 - Specialized Items Chilled	...04	
Q#21 - Lower Cost Of Food	...05	
Q#22 - Reduce Spoilage	...06	
Q#23 - Cook Food Shorter Time	...07	
Q#24 - Doesn't Change Taste	...08	
Q#25 - Doesn't Change Nutrition	...09	
Q#26 - Ease World Hunger	...10	
(Don't Know/None)	...(11)	

28. Now considering all of the arguments and facts I've presented about this food processing technique, do you feel that you would have a major concern, a minor concern, or not concern if it were to be used for foods you eat? (open-ended)

(Ask Q#29)------------------Major concern................1 (71)
------------------Minor concern................2
(Skip to Classification Section)-----------------No concern................3
-(Undecided/Don't know)................(4)

29. What are they? (open-ended and probe fully)

______________________________ ______(72)

______________________________ ______(73)

____

____

____

What others? ______________________________ ______(74)

______________________________ ______(75)

____

____

Now I have a few final questions just for classification purposes.
(Interviewer: Go to Page 1 and complete Classification Information.)

RADIATION
STERILIZERS
INCORPORATED

September 25, 1984

Hon. Marilyn Lloyd, Chairman
Sub Committee on Energy Research & Production
U.S. House of Representatives
Committee on Science and Technology
Suite 2321 Rayburn House Office Building
Washington, DC 20515

Dear Ms. Lloyd:

Attached are my responses to the supplemental questions forwarded with your September 20, 1984 letter. Each question is addressed in the order presented.

I appreciate the Committee's continued interest in radiation processing, and food irradiation in particular. I hope these answers will assist the Committee in the decision making processes. Please feel free to contact me if additional information is required.

Sincerely,

Allan Chin

Allan Chin
President

AC/tb

RADIATION
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Minority Questions

1. The major food irradiation research in this country was sponsored by the Government at the Army facility in Natick, Massachusetts during the 1940's. Additional studies have been carried out by the University of Hawaii and University California of Davis.

At the international level the International Atomic Energy Association, the World Health Organization, and others have sponsored and are sponsoring food irradiation programs. Most of the information generated by these organizations is available from the IAEA headquarters in Vienna.

The IAEA regularly sponsors programs and conferences on food irradiation where much of this information is presented. The last conference was in Hawaii November 1983. The next conference is scheduled for Florida in early 1985.

2. The only two viable sources of gamma rays are cobalt-60 and cesium-137.

Cobalt is produced in nuclear power reactors by exposing cobalt-59 to a neutron flux where a neutron is added to the nucleus to generate cobalt-60.. Cobalt production therefore requires the access to a nuclear power reactor.

Since AECL controls the reactors in Canada, it is able to produce cobalt-60. AECL currently supplies approximately 95% of the world's supply of cobalt-60, and enjoys a monopoly position.

The U.S. Government has several reactors, but only the ATR in Idaho Falls has been made partially available to produce cobalt-60 for U.S. industry demand.

The commercial reactors, because of specific design restraints or economic reasons, will not consider the production of cobalt.

England and France at one time generated small amounts of cobalt. Today both purchase their cobalt from AECL.

Outside of the government reactors, there does not appear to be a viable source for neutrons to manufacture cobalt. If the government reactors were dedicated to cobalt production, they could meet the industry demand.

The only other source for gamma rays is cesium-137, a product of the waste fuel rods from reactors. The U.S. DOE has embarked upon a Recovery and Re-Utilization program as a method of radioactive waste management.

Currently they have demonstrated that they can recover the cesium from the government reactor waste fuel by separating and encapsulating over 70MCi at Hanford, Washington. RSI is working closely with the DOE to utilize this material in its facilities.

This source of gamma rays however appears to be limited by the amount of cesium on hand which will be exhausted in about 2 years. The potential amount of cesium from commercial waste fuel rods is virtually endless. However, it is estimated that no additional cesium will be recovered in this century.

The use of cesium is therefore only a short term source for gamma rays unless the government accelerates its cesium recovery program to use radioactive waste materials for beneficial uses.

3. RSI has responded to requests for quotation from the DOE to build a Transportable Commodities irradiator and a Citrus Fruit Irradiator in Florida. Both units are designed for using cesium as the source material. We were not successful in these bids.

4. RSI applied to the NRC for approval to use cesium-137 on April 3, 1984. On August 14, 1984 Bernie Singer in a phone conversation told me that my application was approved, and a letter to that effect was being drafted. As of September 25, 1984 I have not received this letter in spite of several inquiring phone calls to Singer's office.

In discussion with U.S. DOE personnel no additional cesium is planned to be made available in this century. Existing inventories will be depleted in two years. Unless steps are taken by the government to re-activate the cesium recovery program, cesium cannot be considered to be a viable, continuing source of cesium.

5. The industry is divided into companies which own and operate facilities for their own use, and companies which provide contract services.

In the first category there are seven companies which collectively operate 16 facilities.

In the second category there are 5 companies operating 17 facilities.

The total revenue of the service companies is about 15 million dollars per year. The revenue of the other companies is not relevant nor available.

The use of radiation to sterilize medical products was about 5% in 1977. Today it is about 40%, and estimated to grow to 70%-80% during the next few years. These figures include both types of facilities.

The contract service company sales have grown at an average rate of 30-40% per year since 1977.

RADIATION
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Additional Questions for Mr. Allan Chin

1. The Atomic Energy of Canada limited (AECL) currently controls approximately 95% of the world's industrial cobalt supply. Current costs are about $1.00 per curie.

There are major additional costs and some risks involved with using cesium. All existing facilities have been designed to use cobalt. Major modifications would be required to enable the use of cesium. Additionally shipping costs for cesium will be much higher. Typically shipping and loading costs will be about ten times higher than for cobalt, and could equal or exceed the current cost of cesium.

The major risk involved with using cesium is the possibility of a leaky source which would result in substantial financial consequences. This risk is demmed to be very slight..

The larger cesium half life is certainly a benefit over cobalt and will result in a financial advantage. However, because of the lower cesium energy, seven times as many curies of cesium are needed. The current proposed cesium leasing program is based upon a 10¢ per effective curie cost and an annual 7½% per annum lease rate. These terms make it advantageous to consider the use of cesium in todays market.

A detailed cost analysis would be required to determine the precise break even point between cesium and cobalt. This point will vary from facility to facility, and it would be difficult to set a single cesium cost which would be equitable to all facilities.

In general, the current cost structure would induce me to select cesium over cobalt. I also feel that cesium must always sell at a considerable advantage over cobalt because of the risks and problems involved.

2. AECL has maintained a virtual monopoly position in both cobalt and equipment sales since the inception of the gamma sterilization industry during the 1950's. RSI was formed 5 years ago and decided to design its own equipment to the dismay of AECL. Initial cobalt sales appeared to be fair and equitable to RSI.

However, after RSI made an equipment sale to Cobe Laboratories in Denver in 1982, AECL informed RSI that they considered them to be a competitor. As such cobalt prices would be higher and in the event of a shortage, AECL's equipment purchasers would be given priority on available cobalt supplies.

These statements were made to other potential equipment purchasers, and as a result, RSI lost several potential sales. In general, most industry experts consider RSI equipment superior to AECL's.

RSI has paid higher prices for cobalt and currently is on a very low allocation of cobalt for the next year. As a result our facility construction program has been drastically curtailed. RSI is also losing some of their customers because of non-supply of cobalt. In many cases the losses are to competitors who are favorably treated by AECL because they use AECL equipment.

RSI has been attempting to purchase cobalt from Neutron Products Incorporated in Maryland, for about a year. Neutron Products does not produce cobalt, but buys surplus cobalt from the government or has it activated by the DOE in Idaho Falls. In total they can supply quantities of cobalt less than one million curies (1MCi). We have not been able to consummate the sale of even 200,000 Ci of cobalt. The major reason is that Neutron Products wants RSI to guarantee the purchase of a like amount for the next 8 years. We feel this is unreasonable, and are beginning to question whether they even have 200,000Ci to sell.

RSI has a 5MCi cobalt order with the DOE to be activated in the Idaho Falls ATR Reactor. However at current production rates, it will take at least 10 years to fill this order.

RSI has been also negotiating with the French to purchase cobalt. They have relatively small amounts (less than IMCi) and their prices are 50% more than AECL. The primary source of their cobalt is AECL.

In summary RSI is in desperate need of cobalt or other sources of gamma rays. We have exhausted all available sources of cobalt. Little to none is or will be available to RSI for the next year. RSI has also unsuccessfully approached other facility owners with the offer to purchase any excess isotope they may have.

3. Food irradiation will provide better quality product at lower costs. The better quality will be a result of decreased spoilage rates. These decreased spoilage rates could lead to lower costs if the producer and retailers pass along the resultant savings. Decreased spoilage rates will also directly benefit the consumer financially, and minimize potential health hazards.

It will become economically feasible in those instances where it is the only viable treatment process, i.e. if EDB is outlawed, or where the economics will justify it i.e. for high unit cost products with high spoilage rates.

4. There is a significant resistance to irradiated food, and it can be attributed in large measure to ignorance. The involvement of the Federal government or any other organization in public education will certainly help to dispel any possible fears of irradiated foods.

5. In general acceptable costs to irradiate food are in the 3-6¢lb range. Typical break even costs for large scale radiation facilities are around 1-1.5 million dollars per year. Assuming that a 100,000 rad dose is required, about 100,000 to 150,000 Ci of cobalt or 700,000 to 1,050,000 Ci of cesium would be required. The number of additional curies for higher production rates is directly proportional to the through put.

A mobile facility would not be feasible because it cannot be built big enough to process any reasonable production quantities.

In food irradiation, the quantities will always be very large and processing will be performed in large fixed facilities. Most food irradiation will probably be performed in captive in-house facilities. The use of contract facilities will probably be very limited because transportation and handling costs can become prohibitive.

Because of the lower dosages used for many food applications, the isotope requirements can be relatively small and not a large factor in the operation of a food irradiation facility.

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October 8, 1984

The Honorable Marilyn Lloyd
Chairman, Subcommittee on Energy
Research and Production
U.S. House of Representatives
B-374 Rayburn House Office Building
Washington, D.C. 20515

ATTENTION Ms. Debbie Martin

Dear Madam Lloyd:

In response to the questions in your letter of September 20, 1984, I would like to make the following comments:

- *Would you care to estimate how large the market for radiation sources might be in the next few years compared to current available supplies?*

  It is difficult to reliably predict the demand for gamma sources in the U.S. for food irradiation at the present time because of the uncertainty in regulatory approval, public acceptance, and development of alternate processing techniques. The major present use of gamma sources in the U.S. is for sterilization of disposable medical products. At present this country irradiates about 35% of these products and it is estimated to increase to 90% by 1990. This additional load would require about 450 MCi of cesium-137 or about 90 MCi of cobalt-60. If the approval of food irradiation by FDA and a reasonable penetration of the market is assumed, the demand for gamma sources is estimated to be about 300 to 400 MCi of cesium-137 for irradiation of agricultural products in the U.S. This is based upon irradiation of citrus fruits, apples and cherries (for export), pork, chicken, and cattle hides. Such an estimate does not consider many other potential products that may be benefited by irradiation. Thus, the total demand by 1990 in the U.S. could be as much as 700 to 1000 MCi of cesium-137 or an equivalent amount (140 to 200 MCi) of cobalt-60.

  The current sole source of cesium-137 is the 77 MCi of encapsulated cesium chloride stored at Hanford. Future processing of defense fuels at Hanford could supply another 40 MCi by 1990 without additional facilities and equipment. Another 100 MCi is contained in the waste at Savannah River and an additional 100 MCi will be generated by 1990. However, no facilities are available at Savannah River for purification or encapsulation. Such facilities would be required or the cesium would need to be transported to Hanford for encapsulation to use this potential source. In addition, large quantities (up to 1800 MCi) are contained in spent power reactor fuel, but recovery of this material would require a commitment to spent fuel processing or other methods of treating spent fuel. Cobalt-60 supply from Atomic Energy of Canada, Ltd. is expected to increase in the future to perhaps 100 MCi/year, but these supplies go to meet worldwide needs. In my opinion, there will continue to be a strong demand for cesium-137 sources in the future, justifying an evaluation of recovery from commercial spent fuel. Studies should also be conducted to evaluate the potential of domestic production of cobalt-60 sources. It appears that both cesium-137 and cobalt-60 sources will be required to meet present and future needs.

- *Is the substantial experience that has been gained over the years in food irradiation using Co-60 transferrable to Cs-137? What are the practical differences in using these two radiation sources?*

Data gained using cobalt-60 are directly applicable to irradiation with cesium-137. Cobalt-60 gamma rays are somewhat more energetic than those from cesium-137 (1.17 and 1.33 versus 0.66 MeV), and thus, are slightly more penetrating. Use of cesium-137 will produce a slight increase in the ratio of the maximum to minimum dose received by the product, but will not significantly affect the process. The major change will be in the irradiator design to accommodate the added source volume. Since the cobalt-60 sources are generally about 4 or 5 times greater in specific activity (Ci/g) than cesium-137 and since about 1/4 to 1/5 as many curies of cobalt-60 are required to obtain a comparable dose, the cobalt-60 sources occupy about 1/20 the volume. The increase in source volume using cesium-137 does not appear to be significant in present irradiator designs because of the large free volume available.

- *What do you think are the current barriers to more commercial use of food irradiation in this country?*

The initial barrier is acceptance by FDA. Assuming that FDA approves the present proposal, then food irradiation will increase markedly. Care will be needed to assure that sufficient studies have been conducted to use irradiation in a meaningful way. Some promoters think that irradiation is a panacea for all of our food export and spoilage problems. This is not the case. We must carefully assess the benefits and then define appropriate parameters (such as dose, and temperature) which each product should receive. Public acceptance of food irradiation will remain a barrier until the benefits are clearly shown to be greater than the perceived risk. Licensing of the irradiator does not appear to be a significant barrier at the present time.

- *Could you use the Cs-137 in the form that is currently available from DOE? Would another form be more suitable to your needs?*

  The cesium-137 capsules presently stored at Hanford are usable in their present form and should be used in this form. They are not optimized for irradiator use but are satisfactory in terms of safety, efficiency, and utility, and the benefits of reincapsulating them would not justify the cost. Fission-product cesium from future processing of nuclear fuels should be encapsulated in a form specifically optimized for irradiator use.

- *Could you elaborate on the machine-generated sources of irradiated energy as alternatives to radioisotope sources? What are the relative advantages? Are they available now?*

  Machine-generated sources are presently available and in use in special applications where low penetration is required. Present machine sources use high-energy electrons with the penetration depth limitation of a few millimeters. Thus, they are not applicable for most food products. On the other hand, some commodities, such as grains, may use electron-beam sources very effectively. Conversion to x-rays using targets is possible but not very efficient. Thus, the use of gamma-producing isotopes appears to be preferred for bulk food. Machine-generated sources have the advantage of a carefully controlled monodirectional source which can be turned on or off.

Minority Questions

1. *What amount of cobalt-60 is supplied to the world by the Atomic Energy Canada Limited program?*

   According to available information, the Atomic Energy of Canada Ltd. produces about 28 MCi/year of cobalt-60. Since the demand exceeds this capacity, they are taking steps to increase this supply to about 100 MCi/year, if possible.

2. *You state that "the present DOE policy stimulates the development of food irradiation by participating in the construction of demonstration irradiators." How does this take place? To what extent is industry involved in the construction of demonstration irradiators?*

   Because of the past uncertainty of government control of food irradiation and public acceptance, private industry has been hesitant to invest heavily into facilities to demonstrate the process. Therefore, Congress has appropriated some funding for the construction of small demonstration irradiators. At the present time, a demonstration plant, primarily for citrus fruit irradiation in Florida, is being designed. USDA will likely be the licensee of this plant. Also, an irradiator for control of trichinosis of pork is being designed for construction in Iowa. Other demonstration irradiators have been suggested for the Northwest and California. In each of these instances, industrial organizations are involved, and it is my understanding that they will be expected to contribute to the cost of the demonstration.

3. *If cesium-137 is not available from reprocessed spent nuclear fuel, what other sources are available for that material?*

The only economical source of cesium-137 is from spent defense and commercial power reactor fuel. If sufficient cesium is not made available from these sources, then it would be prudent to consider other means of activating cobalt in our government production or power test reactors. There does not appear to be sufficient incentive for the utilities to produce cobalt-60 in power reactors.

Thank you and the other members of your committee for your continued interest in this important subject. If I can be of further assistance in supplying information on this topic, I would be happy to do so.

Very truly yours,

Garth L Tingey

Garth L. Tingey
Technical Leader
Ceramics Technology and Nuclear
Byproducts Section

ADDITIONAL QUESTIONS FOR DR. JACEK SIVINSKI

1. In your view, will the irradiation facilities already contemplated within the scope of the Byproducts Utilization Program satisfy the remaining research requirements for technology development and transfer?

Answer

The irradiation facilities currently proposed under the auspices of the Byproducts Utilization Program (BUP) include the TransPortable Cesium Irradiator (TPCI), the Cesium-137 Agricultural Commodities Irradiator (CACI), and the pork irradiation facility. These facilities have already advanced to the design or fabrication phase of their schedule. Although the general purpose of the irradiation facilities remains the same--to provide and transfer a technology which helps keep food plentiful and wholesome--each facility is uniquely different in terms of food groups to be studied, degrees of emphasis on research and demonstration priorities, support equipment and service, etc. These differences in food irradiation protocols necessitate that special design efforts be afforded each facility. The facilities vary in design and purpose to the degree that the food industries themselves vary. It is anticipated that under proper management and direction, each of the BUP facilities will go a long way toward answering the specialized research needs required by their respective food industries for technology development and transfer. However, building the facilities and then abandoning them would be imprudent at best and the commitment by Congress for initial support and nurture must be made and honored in order to develop their potential for technology development and transfer.

Irradiation can provide disinfestation of agricultural products and substitute for chemical pesticides which may leave toxic residues. Development of irradiation quarantine treatment protocols must be conducted ~~to~~ with *live* insects and *fresh* produce. It would not be prudent to conduct irradiation quarantine treatment protocol trials in the U.S. where accidental release of exotic insects could cause economic damage and tropical produce is not readily available. For these reasons it is suggested that an additional irradiation quarantine treatment facility be developed at a site where the pests and produce are readily available, such as Central America. The Agency for International Development under the Caribbean Basin Initiative would likely have interest in satisfying the need for an appropriate irradiation quarantine development facility at a site where multiple insect pest species of agricultural economic importance are endemic and where a wide variety of tropical crops are available.

2. What effects do regulatory actions by our government have on the use of food irradiation abroad?

Answer

The effects are significant. Regulatory actions by our government produce both positive and negative signals on the use of food irradiation worldwide.

One example of these effects occurred with the banning of EDB residues in foods. The EDB ban caused a major dislocation of milestone and commodity-specific programs for the Caribbean Basin Initiative and increased significantly the interest there in irradiation as an alternative to fumigation. The U.S. AID is vigorously pursuing irradiation feasibility studies for countries in the Caribbean Basin and Central America to soften the impact of the EDB ban.

The rest of the world awaits the forthcoming FDA decision on food irradiation. Although United States (U.S.) FDA and other representatives to the Joint WHO/IAEA/FAO Expert Committee and the Codex Alimentarious Commission helped develop the "one megarad absorbed dose" position as wholesome for human consumption and the position that "irradiation is a process and not an additive", our policymakers have taken a very cautious, possibly unwarranted position. The conservative attitude of the FDA has slowed down the regulatory and acceptance processes in some nations and completely stopped it in others.

Because of the high regard that other nations hold for research in the United States, they tend to take cues from the U.S. more frequently than they should. They frequently tend to accept policies and guidelines adopted by the U.S. without regard for differences in perspective, priorities, or basic need. Though a great deal of expertise in matters of safety and health does exist in the U.S., malnutrition and starvation rarely become domestic consequences of food loss due to a banned fumigant or nonadoption of a new technology as might be the case in a lesser developed country.

The tendency for some countries to accept U.S. regulatory actions may also be due to the lack of qualified technical personnel available to reevaluate a data base of information under their own set of priorities. Another reason is that historically, much of the foreign research work was accomplished through PL 480 funding. Thus, U.S. (e.g., FDA) constraints were imposed on some of the scientific research in these countries and contributed to adoption of U.S. positions.

There is need for U.S. Government agencies to collaborate in regulatory and research and development activities in applying the benefits of food irradiation processing (disinfestation, delay of ripening, sprout inhibition, etc.) on tropical crops not widely grown domestically. Lack of coordination in regulatory and development programs has mitigated the benefits of the Caribbean Basin Initiative and has been politically detrimental to U.S. efforts in the Central America and Caribbean region.

3. You and Dr. Tingey have both articulated the point that insufficient isotope supplies could be a limiting factor in technology utilization. Would you care to estimate how large the market for radiation sources might be in the next few years compared to current available supplies?

Answer

The number of curies of cesium-137 that are encapsulated and currently available for use in irradiators is approximately 70 million. The quantity of isotope that has been requested by industry and DOE within the last 3 months is almost double that which is available. Supply currently does not satisfy the demand, and this shortfall is not expected to be remedied in the near future. Various scenarios for irradiation technology have been formulated, and assuming isotopes are available, one that I find credible suggests that five or six times the current production capabilities are needed to minimally satisfy projected medical product sterilization needs and begin to realize the food irradiation potential.

4. Is the substantial experience that has been gained over the years in food irradiation using Co-60 transferrable to Cs-137? What are the practical differences in using these two radiation sources?

Answer

The two primary considerations in evaluating radionuclides are the radioactive decay characteristics and the interaction of the emitted radiation with target matter.

Every radionuclide is unique in its decay, and is characterized by a half-life and a radiation spectrum. The radiation spectrum determines the quantity of radionuclide needed to provide the desired dose rate to a product, and the half-life determines the rate at which the radionuclide decays. For cobalt-60 and cesium-137, both of which are gamma emitters, those differences in radionuclide decay do not preclude either isotope from being used in an irradiator. They can be used interchangeably by simply adjusting various engineering or design parameters such as the source geometry, the product depth or thickness, the length of time for product irradiation, the product path around the source, and the distance between the product and the source. The differences in half-life, photon energy and number of photons per disintegrations are compensated for in the engineering design parameters and the frequency of source replenishment needed due to decay (half-life) differences.

With regard to the interaction of the emitted radiation with target matter, the substantial equivalency of a cobalt-60 and cesium-137 gamma is quite well established. The emitted gammas from the two isotopes are close enough in energy that the basic attenuation and multiple scatter interaction processes are very similar. Thus cobalt-60 and cesium-137 produce the same technical effect in the commodity being irradiated. Although the similarity in material compatibility is generally accepted in the scientific world, it is not uncommon to have to "reprove" that fact to a cautious entrepreneur who may be at the threshold of a large investment in cesium technology.

5. What do you think are the current barriers to more commercial use of food irradiation in this country?

Answer

One barrier is the lack of a good education program on irradiation for the food industry and consumers. Once the producing/processing/marketing industries accept the technology because of valid business or social reasons, and the consumer demand is made, then industry will become convinced that they cannot afford to pass up the technology.

Another barrier, and one which has already been discussed, is the snail's pace at which the FDA addresses the whole irradiation issue, in spite of the already internationally approved Codex Standard. Some of the specific issues which still need to be resolved are labeling, irradiation of commodities other than fresh fruits and fresh vegetables, and the maximum permissible absorbed dose level.

A third barrier which could severely impede the actualization of the potential of the technology for human benefit is the lack of a vigorous program to face the issues related to isotope supply, and the potential for the program to founder for this reason. Production of isotopes as "weapons for peace" should have at least the same moral commitment as production of "weapons for war" in order to keep the peace. I am continually surprised that Congress does not mandate such activity on a continuing basis instead of throwing some crumbs here and there or most frequently not at all. It is a revealing exercise to compare the nuclear weapons budget to build systems you hope to never use and the budget to develop the nuclear potential for an improved human condition which the world desperately needs.

6. Could you use the Cs-137 in the form that it is currently available from DOE? Would another form be more suitable to your needs?

Answer

The form of cesium-137 available from DOE is adequate and most certainly useable, and in fact, is currently being used. Admittedly, cesium-137 capsules, or WESF capsules, were originally designed for long-term pool and geological media storage, and as such are not as efficient as they could be for irradiation of commodities. However, it is estimated that any re-encapsulation into a more efficient package of any cesium now encapsulated would be prohibitively expensive. But, any future packaging of new cesium should first look seriously at a more efficient capsule and weigh the cost/benefit of the conversion.

7. Could you elaborate on the machine-generated sources of irradiated energy as alternatives to radioisotope sources? What are the relative advantages? Are they available now?

Answer

High energy electron beams for radiation processing is now a proven industrial process. Four and 5-MeV electron beam sources are commercially available at powers up to 200 kW. Higher energy machines are desirable but are much less readily available. As a general rule, electron beam accelerators show process viability in applications characterized by relatively large product throughputs that are conveyed past the beam in thin layer bulk form, low-density products with relatively thin cross sections, and products requiring only surface or subsurface treatment. However, it is well known that electrons in the energy range from 0.2 to 10 MeV have limited penetration and cannot be used to process densely packaged or relatively large size products, including some medical devices and many foods. Because of the earlier maturity of isotope irradiator technology, the radiation sterilization of most medical devices has been historically accomplished using the more penetrating photon beams from isotopes such as cobalt-60.

An alternative to gamma emitting isotopes is to use machine-generated bremsstrahlung photons. Bremsstrahlung photons are similar to isotope photons in form and penetration and are produced when energetic electrons are slowed down or stopped in a suitable target material such as tungsten. Whether or not electron beam or bremsstrahlung accelerators are particularly applicable for an industrial process is often fundamentally a question of economics. Usually, relatively high throughputs are required before the cost per unit volume of material irradiated to a given dose becomes less than the associated cost using isotopes.

In light of the ever increasing demand and relatively short supply of isotope, it is important that accelerators be used in future programs to which they are especially suited so that the isotopes can be freed for their most productive uses. The accelerator and isotope roles should be more finely focused in the future thereby using the right tool for the right job to the benefit and growth of both systems. We simply will not be able to afford the luxury of using them as interchangeably as we do now.

In view of the economic importance to the U.S. foreign exchange earnings from grain exports and the political importance of a growing PL 480 program, it would seem prudent to begin a U.S. research and development program in the use of machine generated irradiation of grain. The U.S.S.R. at Odessa has been experimenting with relatively large scale machine generated irradiation for grain disinfestation and is now expanding the Russian program. Because of the high throughput capacities of commercial grain handling systems in the U.S. and the probable feasibility of thin layer machine generated irradiation of grain, future potential benefits to the United States are unknown in the absence of a U.S. R&D effort in this area.

MINORITY QUESTIONS

1. Please relate the "megarad" to normal radiation exposure.

Answer

The "megarad" (or one million rads) is a measure of absorbed dose. Various absorbed doses of ionizing energy can be used for different purposes (technical effects) in food preservation. Very low doses up to 100 thousand rads can be used for inhibition of sprouting, insect disinfestation, parasite inactivation in meat and fish, and delay of ripening. Medium dose levels from 100 thousand rads to one megarad are useful for extension of food shelf-life, reduction of microbial load, especially such pathogens as Salmonella, and improvements in technological properties of food. High dose levels from one to five megarads are useful for commercial sterilization and elimination of viruses.

2. In the food irradiation program you state that "consumer education has to be a major task that must be properly developed and administered." By whom should this task be performed? What period of time would be involved? What expense do you associate with consumer education?

Answer

Before a consumer ever has an opportunity to consume an irradiated and enhanced-value product, it has to be processed or manufactured. The food companies have a significant capital equity, familiarity, and comfort with existing technology, trained personnel, and distribution and marketing networks which took many years of hard work to develop and to stay competitive in. These industries understand public acceptance and use professionals in market development and advertising to achieve consumption of their product. Consumer acceptance can best be developed by the industry while the research and development community, in concert with national and international agencies, can and should provide the industry every assistance in reaching a consensus on the validity of food irradiation as an appropriate and useful technology.

All parts of the food industry chain must be involved in the consumer acceptance plan from the producer, to the processor, to the distributor and the marketer, because each segment of the industry must have credibility and a relationship with each other. Much like a team effort, no one segment becomes insignificant and all contribute. Each segment can speak out knowledgeably and vigorously on the particular advantages and risks his group would experience in adopting food irradiation and what they could do to encourage consumer acceptance.

Helping industry to administer the consumer education plan is an issue that I feel the Congress should recognize and pursue. Although various approaches can be used to help industry adopt and subsequently sell the technology, one possible course of action is for the Congress to organize a bipartisan oversight committee to analyze the situation in depth. Over a very short time frame, on the order of 6 months, the committee would determine a definitive course of action with regard to future funding, appropriate legislation, information dissemination, or any other appropriate activities needed on a national level to help transfer the technology to industry and the consumer. Members of the oversight committee would include representatives from various governmental agencies. Active support from industry should also be solicited since they can make a significant contribution, and a plan that they helped develop would be easiest to implement.

Because of the role the U.S. Department of Agriculture plays in food and agriculture research and development and the potential impact food irradiation will likely have on U.S. food marketing, USDA should reevaluate its position of not vigorously supporting a consumer education dialog with the American public.

3. What impediments will be imposed on the food irradiation program, and by whom?

Answer

One impediment will always be people who either through ignorance or by choice, find fault with the program. But if their questions are sincere, I believe we have the credible answers they need that could help them develop a rational perspective on the issues they raise.

A second impediment could be institutional or governmental policy based on political or social issues which prevent source acquisition, source transport, licenseability of an irradiator facility, etc. One example of this would be the inability to acquire existing isotope because of policy decisions not to condition spent fuel rods and extract the useful radionuclides.

A third impediment is the reticence of the Departments of Agriculture and Energy in pursuing and developing programs that are clearly indicated to be necessary. My strong impression is that they feel this position is indicated by the Office of Management and Budget and that they discern a lack of champions in the Congress. An example is the lack of adequate funding needed to fund research, transfer technology to industry and to develop a consumer awareness plan. This becomes even more convincing to them in light of the excessive funding allotted to programs which, in my perhaps biased opinion, offer much less for humanity than does food irradiation.

DE/052/33R

United States
Department of
Agriculture

Agricultural
Research
Service

Office of the
Administrator

Washington, D.C.
20250

October 4, 1984

Honorable Marilyn Lloyd
Chairman, Subcommittee on Energy
  Research and Production
Committee on Science and Technology
Suite 2321, Rayburn House Office Building
Washington, D. C. 20515

Dear Madam Chairman:

In response to your request of September 20, enclosed is the additional information for inclusion in the record of the July 26 hearing on the Status of the Technical Infrastructure Required to Support Domestic Food Irradiation.

Sincerely,

for M. E. Carter

T. B. KINNEY, JR.
Administrator

Enclosure

Q. Do adequate facilities and hardware exist to conduct the necessary R&D on the downstream effects of irradiation on the exposed products?

A. The Agricultural Research Service has access to laboratory and small scale irradiators to evaluate the treatment effectiveness on controlling insects and studies on phytotoxic effects on the exposed commodity. These small units are not suitable for commercial use, but they are sufficient to develop data necessary for quarantine treatment schedules.

Q. Does adequate instrumentation exist so that dosages can be monitored and controlled within the allowable limits?

A. Yes, adequate dosimeters exist to monitor irradiators.

Q. What do you think is the minimum size for a commercial food irradiation facility in terms of curies of radiation? How many facilities would be required if irradiation became the predominant method of disinfestation of foodstuffs in the United States? How many additional facilities might be needed if irradiation were also used for preservation of foodstuffs?

A. An estimated source size for a commercial irradiation facility will be between 0.5 and 3 million curies of Cobalt-60 or for a Cesium-137 source between 2 and 15 million curies. The actual source size will depend upon the density of the product, the processing dose, the efficiency of the irradiator and the number hours per week operated.

We do not have an estimate on how many irradiation facilities would be required if irradiation became the predominant method of disinfestation. As technology is developed to determine which fruits or other products contain insects, it will be possible for the commercial processor to treat only the commodities infested. This screening method can significantly reduce the number of treatment facilities which may be needed.

At this point, there is no reasonable basis to predict how many irradiation facilities would be used for preservation of foodstuffs.

Q. The great majority of the health research on food irradiation has been done on food irradiated with Cobalt-60. Is that body of research applicable to irradiation with Cesium-137?

A. Research conducted on the effectiveness of irradiation with Cobalt-60 to control pests or organisms in food products is applicable to a Cesium-137 source. This is because the radiation effects in food are primarily a result of the secondary electrons produced from the primary gamma irradiation. The USDA will defer to the Department of Health and Human Services for comments on health effects.

Q. In your opinion, how long will it take the Food and Drug Administration (FDA) to determine the low-dose irradiation regulation once adequate data is in hand?

A. This question must be answered by the Food and Drug Administration.

Q. You mentioned the delivery date to FDA on March 30, 1984, involving studies made by USDA on irradiation of chicken. How much of this information was also made available to interested members of industry?

A. All the studies submitted to the FDA on irradiation sterilization of chicken are now available to any interested party through the National Technical Information Service of the Department of Commerce. A Federal Register notice of this availability will be published in the near future.

Q. Why do you believe the U.S. grain industry has not used irradiation for insect disinfestation.

A. The implementation of grain irradiation by U.S. industry would require a major capitol outlay compared to other treatment methods. To effectively use irradiation for insect disinfestation of grain, would require improved methods to determine whether the grain is infested. Current practices by the U.S. grain industry require treatment for insects only after a particular lot is found to be "weevily." A new insect detection device now under development by the Agricultural Research Service may permit identification of hidden infestations in grain at an early stage of marketing. It is not practical or cost effective to consider irradiation of all U.S. grain because of the large volumes which move through our transportation systems; however, it would be reasonable to consider irradiation treatment only on grain known to be infested.

Department of Energy
Washington, D.C. 20585

October 19, 1984

Honorable Marilyn Lloyd
Chairman
Subcommittee on Energy Research
and Production
Committee on Science and Technology
House of Representatives
Washington, D.C. 20515

Dear Madam Chairman:

On July 26, 1984, Dr. F. C. Gilbert appeared before your Subcommittee to discuss the technical infrastructure required to support domestic food irradiation.

Following that hearing, you submitted written questions for response to supplement the record. Enclosed are answers to those questions which also have been sent directly to the Subcommittee staff.

If you have any questions, please call Diana Diamond or Tom Pretorius of my staff on 252-4277. They will be happy to assist you.

Sincerely,

Robert G. Rabben
Assistant General Counsel
for Legislation

Enclosure

bcc: Ms. Debbie Martin
Ms. Nancy Jeffery

POST-HEARING QUESTIONS AND ANSWERS

Relating to the

JULY 26, 1984 HEARING

Before the

SUBCOMMITTEE ON ENERGY RESEARCH AND PRODUCTION
of the
COMMITTEE ON SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES
WITNESS: DR. F. C. GILBERT

Question

What is the Federal Government's liability in leasing isotopes as opposed to selling them? Does leasing isotopes pose unusual regulatory problems with the Nuclear Regulatory Commission?

Answer

The current sales or lease agreement form DOE/ER-391, Isotope and Technical Service Order Form, Terms and Conditions, number 8, states, "Neither the Government, the Department, nor persons acting on behalf of the Department makes any warranty or other representation express or implied, that (a) materials accepted for technical service will not be destroyed, damaged, lost, or otherwise altered in physical or chemical properties in the process of performing the requested technical service, or that (b) materials furnished under this order (1) will not result in injury or damage when used for purposes authorized by the Department or for any other purpose or use, or (2) will accomplish the results for which they are requested or intended." If the DOE leases rather than sells isotopes, the isotopes would be returned to DOE for disposal.

With respect to NRC's role, it does not appear to us that the leasing arrangement would pose any unusual regulatory problems, since licenses are for possession and do not address ownership of nuclear materials. Actually, the terms of the lease, and the required return of material should serve to reinforce health and safety assurance and to simplify the regulatory process.

Question

Why didn't the Administration submit a request for funding in FY 1985 for the Byproducts and Beneficial Use Program?

Answer

DOE plans for the byproduct and beneficial use program are based on the future funding coming from users of the technology. The DOE, with FY 1984 funds, is completing construction of three pilot cesium-137 food irradiators: the transportable cesium irradiator will demonstrate irradiation on a variety of foods at point of production, initially in the Pacific Northwest; the cesium agricultural commodity irradiator is a pilot-fixed facility that will initially demonstrate irradiation as a substitute for ethylene dibromide treatment of Florida citrus fruits; and the pork irradiator will demonstrate irradiation treatment of pork for the trichina parasite.

The study of irradiated sewage sludge use by New Mexico State University and irradiation work on the City of Albuquerque sewage sludge are also planned using prior year funding. Support for the Department of Defense, using FY 1984 funds, will provide for development of second generation tritium airfield lighting and completion of a demonstration 500 watt strontium-90 radioisotope thermoelectric generator. Since FY 1984 funding will complete these important projects and demonstrate practical radioisotope uses, further funding by DOE for FY 1985 was not planned.

Question

Does the price allow for recovery of all the costs of separating the cesium from the other wastes and putting it in a form suitable for use in an irradiation facility? Are there any statutory or other non-market constraints on the price that you can charge for Cs-137?

Answer

The price of 10 cents per curie for cesium-137 currently existing in the DOE inventory at Hanford has been the published price for several years. This material was originally separated from high-level wastes at Hanford and encapsulated as part of waste management operations with the intent to simplify handling of the wastes.

A fairly recent study conducted by Exxon Nuclear Corporation did identify costs for encapsulation of cesium-137 in a reprocessing facility that was in existence and operation. The incremental costs to process cesium for commercial use in such an existing facility were estimated at approximately 12 cents per curie. Thus, the published price of 10 cents per curie is not unrealistic for such a scenario. It should be noted that for the Hanford operation, the 10 cents per curie price does not represent full cost recovery for future operations. The full recovery costs for cesium processed through Hanford as an isotope production plant operating at full capacity are being studied at this time.

Under the Atomic Energy Act, DOE is authorized considerable flexibility in establishing a price for byproducts produced by Department operations. The only constraints are the criteria for charging set forth in Section 81 of the Atomic Energy Act. The major thrust of Section 81 is that the prices stated by DOE should be on an equitable basis such as to provide reasonable compensation to the Government, will not discourage use of such material or development of a source of supply independent of DOE, and will encourage research and development.

Question

In your testimony, you refer to a small quantity of DOE-produced Cobalt-60 at the Advanced Test Reactor in Idaho. Could you tell us to whom the bulk of that isotope is going and for what application?

Answer

Based on earlier purchase orders, all material shipped so far from the Advanced Test Reactor has gone to Neutron Products, Incorporated, for teletherapy (cancer therapy), medical products sterilization, and commercial irradiation of other products. However, two other firms --Radiation Sterilizers and Radiation Technology, Incorporated--currently have targets in the Advanced Test Reactor.

Question

Your chart on Cesium inventories indicated that 77 million curies are available now and that the potential exists for the recovery of an additional 250 million curies of Cesium from the combined defense wastes at the Savannah River and Hanford plants. Could you provide the Committee information on what it would take to make additional Cesium available for irradiation of food and other commodities?

Answer

In the case of Hanford, in order to purify and encapsulate cesium-137 from PUREX, it would be necessary to upgrade B-plant, including changeout of its filter system. The contractor has estimated that this upgrade, if initiated in FY 1986, would result in encapsulation during FY 1989 at a cost of approximately $20 million.

With respect to purifying and encapsulating cesium from Savannah River, it would be necessary to make design and construction changes to the Defense Waste Processing Facility (DWPF), which is presently under construction. The purpose of the DWPF is to immobilize defense high-level waste at Savannah River for disposal off-site at a geologic repository. A cesium-bearing stream could be separated during DWPF processing of the high-level waste for immobilization. This stream would contain the majority of the cesium-137 but would also contain a large quantity of inert chemicals. The currently planned DWPF process is to incorporate the cesium stream into borosilicate glass. However, the cesium could be separated, purified, and encapsulated into some usable form. This would require additional facilities and equipment. With appropriate funding it is anticipated that these changes could be made on or about the scheduled start-up date for the DWPF. The process, equipment, and facilities to do this have not been determined and would depend on the final form desired. Thus, no cost estimates have been prepared. Limited studies are underway to determine the feasibility of utilizing cesium in a glass form for beneficial applications.

Planning studies are being conducted to ascertain what it would take to make additional cesium available for irradiation of food and other commodities. When the results of these studies are available in FY 1985, we will provide this information to the Committee.

Question

Could you address the action taken by Congress on this program in the FY 1985 budget process?

Answer

Although DOE did not submit an FY 1985 budget request to Congress for the Byproducts Utilization program, the House Appropriations Committee did authorize (see Attachment, Report 98-755, House of Representatives Energy and Water Development Appropriation Bill, 1985, H6956; H.R. 5653, page 120) the expenditure of up to $2 million in FY 1985 for continued support to byproduct irradiator demonstration projects. These funds were directed to be taken from existing DOE waste management funds and did not represent additional appropriations. The Senate Appropriations Committee did not address this issue, but the Senate and House Conference allowance was as proposed by the House.

In order to reflect the desire of the House Committee to continue program activities, DOE is considering the preparation of a reprogramming request to make available operating funds from funds previously identified for byproducts capital appropriations.

HAC

98TH CONGRESS
2d Session

HOUSE OF REPRESENTATIVES

REPORT
98-755

ENERGY AND WATER DEVELOPMENT APPROPRIATION BILL, 1985

MAY 15, 1984.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BEVILL, from the Committee on Appropriations, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany H.R. 5653]

The Committee on Appropriations submits the following report in explanation of the accompanying bill making appropriations for energy and water development for the fiscal year ending September 30, 1985, and for other purposes.

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DEFENSE WASTE AND BYPRODUCT MANAGEMENT

The defense nuclear waste management program includes near-term and longer term activities to assure that existing and future nuclear waste from Federal Government program activities can be isolated from the biosphere and pose no significant threat to public health and safety. For the near-term, the wastes are managed through interim storage facilities with a high degree of integrity. Simultaneous efforts are proceeding on development of technology and processes for long-term disposal. The program also includes several related efforts for developing beneficial uses of by-product materials from defense wastes, decontamination and decommissioning of facilities and transportation of special nuclear materials.

The Committee recommendation for defense waste and by-product management totals $727,371,000 which reflects an increase of $46,271,000 compared to fiscal year 1984 and a decrease of $25,400,000 from the Administration's budget request.

The Committee recommendation reduces the construction funding for project 81-T-105, Defense waste processing facility, $15,000,000 and project 77-13-F, Waste isolation pilot plant, $10,400,000. These reductions may require some delay and stretch-out of construction.

The Committee's recommendations do not include any new construction for beneficial use of defense waste. However, the Committee's recommendations for Defense Waste Management include up to $2,000,000 to provide the operational follow and evaluation of the irradiators constructed and nearing construction in fiscal year 1984. In addition, the Committee directs the Department to complete a study of the construction of a new irradiation facility or adoption of an existing facility at the Department of Agriculture's South Central Agriculture Research Center at Lane, Oklahoma. The Department should work with the Agricultural Research Service to determine the appropriate size and estimated cost of an irradiator for fruits, vegetables, green animal hides and other agricultural products of the South Central United States area to be served by the research center.

RECOMMENDATION SUMMARIES

Details concerning the Committee recommendation, current year estimates and the budget request are shown in the following tables:

shall be made available for nuclear safety activities.

Magnetic fusion

The conferees agree to provide $440,138,000 for magnetic fusion research activities. The conferees direct that the Department seek international collaboration and financial participation in future large-scale research devices. The conferees concur in the Senate report language requiring a new comprehensive program management plan and direct that no funds be available for other than conceptual analysis activities related to fusion concepts not currently funded in the magnetic fusion program.

Supporting research and technical analysis

The conferees direct the Department to comply with the Senate report language regarding a $2,300,000 grant for design and related activities for a science facility at the University of Oregon. The Department is to include funding to initiate construction of this facility in the FY 1986 budget request.

University research support.—The conferees agree to provide $2,000,000 for low-enriched uranium at university research reactors and to comply with the House report requirement in this program.

General and ADP reductions

The conferees have agreed to various ADP and other general reductions where it was apparent that available or *deferred* funds, savings, program slippage or other sources would be available to offset the requirement for new appropriations. The Department may, to the extent necessary, offset reductions proposed in the ADP program with other program reductions subject to prior approval of the Committees on Appropriations.

Amendment No. 46: Restores language proposed by the House relating to a supercomputer center at Florida State University.

The conferees expect the Department to use standard Federal competitive procurement practices in the acquisition of supercomputers and to apply principals of efficiency and cost effectiveness in selection of systems and locations for Departmental supercomputers.

Uranium supply and enrichment activities

Amendment No. 47: Appropriates $1,650,300,000 as proposed by the House instead of $1,675,300,000 as proposed by the Senate.

Amendment No. 48: Provides estimated revenues of $1,650,300,000 as proposed by the House, instead of estimated revenues of $1,675,300,000 as proposed by the State.

Because of the apparent confusion within the executive branch on the correct interpretation of Uranium Enrichment Appropriation language, the conferees are clarifying their intent. The enrichment appropriation is for a defined level of program activity. The conferees intend that the executive branch obligate each year the full amount as contained in the annual Appropriation Act in order to operate the enrichment enterprise at the level and in the manner provided for in the appropriation. The conferees recognize that actual revenues will often differ from the estimates made at the time the appropriations are arrived at. In the event revenues fall short of estimates, the conferees intend that obligations not be constrained to match revised estimates. Rather obligations are to be consistent with the levels contained in the annual Appropriations Acts. The conferees agree with the House report language in regard to procurement of module modification kits and related materials. Procurement of Set III machines should be done in the most economically cost-effective manner. The conferees agree with the Senate in regard to demand charges levied by TVA.

General science and research activities

The conferees agree to defer, without prejudice, the construction of project 85-R-203, the Continuous Electron Beam Accelerator Facility (CEBAF). The conference allowance includes $3,500,000 in operating expenses to continue research and development and A/E activities to better define the project's scope, schedule and total cost, and for other necessary activities in support of the project. The conferees also agree to increase the funding for High Energy Physics as proposed by the Senate and from within the available funds in fiscal year 1985, the funding for the Argonne Tandem/Linac Accelerator System should be increased by $1,600,000 as proposed by the House.

The conferees agree that the Department shall conduct a workshop on the future of the High Energy Physics programs, and prepare a five-year Nuclear Physics plan as described in the Senate report on the Energy and Water Development Appropriation Bill for 1985.

Atomic energy defense activities

Amendment No. 49: Appropriates $7,333,701,000 for Atomic Energy Defense Activities instead of $7,404,901,000 as proposed by the House and $7,272,925,000 as proposed by the Senate.

Research, development and testing

The conference allowance for research, development and testing operating funds includes $6,900,000 for the Marshall Islands and environmental programs as proposed by the Senate.

Inertial confinement fusion

The conference allowance provides $154,750,000 for operating expenses. Within the glass laser program, $68,200,000 is provided for the program at LLNL, $12,000,000 for the program at KMSF, $7,800,000 for the program at the University of Rochester and $2,700,000 for the program at the Naval Research Laboratory. The conference allowance also includes $41,300,000 for the gas laser program at LANL, $20,800,000 for the Pulsed Power Research at Sandia and $750,000 for supporting research.

Production and surveillance

The conference allowance includes $1,810,900,000 for operating expenses which represents an increase of $145,175,000 over 1984 and is consistent with action taken on individual weapons systems.

Materials production

The conference allowance includes $30,000,000 over the buget request to expedite the development of Special Isotope Separation at LLNL and $10,000,000 to continue construction of the Process Facility Modifications at Richland, Washington.

Defense waste and byproducts management

The conference allowance includes $2,000,000 for the beneficial use of defense waste by-products as proposed by the House.

POWER MARKETING ADMINISTRATIONS

Bonneville Power Administration fund

Amendment No. 50: Restores House language deleted by the Senate allowing the Bonneville Power Administration to transfer to the Bureau of Reclamation funds for fish passage facilities at Prosser and Roza Dams in the Yakima River Basin. In addition, $4,800,000 was provided to the Bureau of Reclamation for construction of the Prosser and Roza Dam Passages. The equitable distribution of funding between BPA and the Bureau of Reclamation will be developed by future authorizing legislation.

The conferees agree to increase BPA borrowing authority for fish enhancement facilities as proposed in the Senate report.

Western Area Power Administration

Amendment No. 51: Appropriates $318,230,000 for WAPA as proposed by the House, instead of $348,230,000 as proposed by the Senate.

Amendment No. 52: Provides that $217,380,000 as proposed by the House shall be derived from the Department of the Interior Reclamation fund instead of $221,821,000 as proposed by the Senate.

Amendment No. 53: Deletes language proposed by the Senate.

Amendment No. 54: Deletes language proposed by the Senate.

The bill authorizes the Secretary of Energy to construct or participate in the construction of such additional facilities as he deems necessary to allow mutually beneficial power sales between the Pacific Northwest and California. The bill further authorizes the Secretary to accept and use funds contributed by non-Federal entities, including investor owned and publicly owned utilities, for that purpose.

The conferees find that there is substantial benefit to be derived from the financing of additional intertie capacity with funds contributed from non-Federal entities. Therefore the Secretary is directed to enter into negotiations with all interested non-Federal entities, including publicly owned utilities, privately owned utilities, the California Department of Water Resources and irrigation districts, for the financing, planning, and construction of a new 500 kV AC line and associated facilities.

The investor owned and publicly owned utilities in California have assured Congress that they will enter into good faith negotiations concerning their participation in the development of a new 500 kV AC line. The conferees interpret these assurances to mean necessarily that all parties will cooperate in the distribution of power to the ultimate consumers. The Secretary shall participate with these non-Federal entities both in their negotiations and in the development of the new line.

Congress expects that the new 500 kV AC line will be built promptly. Accordingly, should any of the participating entities refuse to cooperate or otherwise act to delay construction of the new line, the Secretary is directed to proceed promptly with those remaining interested entities to develop the line. The Secretary is directed to proceed immediately with planning and environmental activities and shall within 120 days of enactment submit to the Congress a conceptual plan for construction of this line. The plan should be designed to maximize the reliability of the total interconnection.

To assure his ability to continue to meet existing obligations, the Secretary may reserve on any portion of any modified and upgraded facilities an amount of transmission capacity the equivalent of the actual transmission capability displaced by such modification and upgrading. To recompense the Federal taxpayer for the value of the contributed Federal facilities the Secretary shall obtain fair compensation from the non-Federal participants. Such compensation may be in the form of transmission capacity on the new 500 kV AC line, monetary payment, or other benefit which the Secretary may determine a fair equivalent. Transmission capacity reserved as compensation shall be used to serve the needs of Federal Government installations. In any event, sufficient capacity shall be reserved to serve the needs of Department of Energy Laboratories and wildlife refuges in California.

Question

One of the barriers to increased use of food irradiation is consumer resistance. Do you see a role for the Department of Energy in public education regarding the wholesomeness of irradiated foods? Are any public education activities planned?

Answer

Public education regarding the wholesomeness of irradiated foods is, of course, a major factor in increased use of food irradiation. The primary responsibility for such education lies with the food processing industry. However, DOE is authorized to further the dissemination of scientific and technical information relating to atomic energy so as to enhance public understanding. We are planning to keep the public informed of the facts involved in food irradiation and to coordinate our activities with those of other interested agencies.

As an official representative to the International Atomic Energy Agency, the DOE participates in the world's largest cooperative food irradiation effort under the Joint FAO/IAEA Division of Isotope and Radiation Applications of Atomic Energy for Food and Agricultural Development. DOE is hosting the FAO/IAEA International Symposium on Food Irradiation Processing in March 1985 in Washington, D.C., the fifth such symposium since 1972 and the first in the U.S.

With regard to activities concerning the wholesomeness of irradiated food, the DOE accepts the 1980 Joint Expert Committee on Food Irradiation of the FAO/WHO/IAEA Report, which recommended unconditional acceptance of irradiated food as completely wholesome for human consumption if the absorbed dose is below 1MRad. This finding should be transmitted to the public, and it is appropriate that the regulatory authorities in the U.S. charged with insuring the wholesomeness of our foods (FDA) be responsible for this public education task.

We are also cognizant that various trade organizations (e.g., AIF, National Pork Producers Council, National Food Processors Association, Institute of Food Technologies, etc.) have public awareness activities on food irradiation.

Question

What do you think would be the difference, in terms of price and DOE's share of the market for irradiation sources, between "full cost recovery" and "fair market value," as the basis for pricing Cs-137?

Answer

There would be a difference, but we are not in a position to analyze the difference at this time without a further determination of what constitutes fair market value, the potential cost benefits to our waste management activities, and the results of a survey of market needs. Action by FDA to allow food commodities to be irradiated would also have a significant impact on the market potential for cesium-137.

Question

How much Cs-137 would a large food irradiation facility require initially, and on an annual basis? How many facilities could be supplied with their initial charge of Cs-137 from your current stockpiles? Would DOE be able to supply the annual needs for that number of facilities? For how many years?

Answer

The quantity of cesium-137 required for a food irradiation facility depends on the specific product being irradiated (especially the density), on the required doses to achieve the desired technical effect through irradiation (i.e., insect disinfestation, sprout inhibition, shelf-life extension, etc.), and on the throughput of commodity to be irradiated. In general, a large commercial irradiator for treatment of fresh fruit or pork products would require from 5-15 million curies of cesium-137 as packaged in the WESF capsules.

Because cesium-137 has a 30-year half-life, annual additions to the initial load of source are not necessary. Such additions are required with cobalt-60 because of its 5-year half-life. Thus, with cobalt-60 approximately 12 percent of the initial source load must be added each year to make up for decay of the cobalt-60 during the year. For cesium, however, such increments must be added every 5 years rather than every year.

The current DOE stockpile of 77 million curies would thus support from 5-15 large food irradiation facilities. However, this stockpile has currently been allocated to other commercial users and is no longer available. Most of the commercial users plan to use their allocation for sterilization of medical products because of the short supply of cobalt-60 and recent OSHA and State action decreasing tolerance limits for chemical fumigants (such as ethylene oxide--ETO) used to sterilize these products. This is appropriate since FDA has yet to approve irradiation of food commodities.

The 5-year incremental needs of these users at this time cannot be met unless DOE processes and encapsulates additional supplies of cesium-137, which is presently under consideration.

Question

Does removing Cesium from reprocessed wastes ease the task of disposing of the wastes? Would DOE remove the Cesium from its wastes in the absence of a commercial market?

Answer

Removal of cesium-137 (a gamma emitter) and strontium-90 (a beta emitter and heat generator) from the processed high-level wastes at Hanford reduces the radiation and thermal loads of these wastes up to about 90 percent. The separated cesium and strontium account for a relatively small fraction of the volume of these wastes so after separation a small volume of highly radioactive, thermally hot byproducts and a large volume of relatively benign wastes must be handled. The concentrations of the heat and radiation loads in a smaller volume have proven to be the better interim waste management handling option at Hanford. This was the reason such separation and encapsulation of cesium and strontium began approximately 10 years ago at that site. At that time, commercial demand for these isotopes was a very minor factor in the decision to proceed with these byproduct recovery operations.

DOE is studying the requirement for ultimate disposal in a repository of the separated cesium and strontium. When the study is completed, we will know the answers to these questions.

Question

Do you feel any more R&D is needed concerning dosimetry used at the irradiation facilities?

Answer

It appears that little additional R&D is needed to develop dosimetry techniques for commercial applications in a food irradiation industry. However, DOE is supporting activities recently undertaken by the American Society for Testing and Materials to develop standards for the implementation of dosimetry technology by commercial food irradiators.

The main research and development effort needed is the determination of unique radiolytic products caused in food by high doses of radiation; however these are not found in significant quantities from the low radiation doses required for parasite removal and other disinfestation applications.

Question

If you were given funds to either develop Cesium-137 or Cobalt-60 singly for the irradiation market, which one would you develop and why?

Answer

It would be inappropriate for DOE and industry to develop and rely solely on one isotope or machine-generated source of radiation to meet the current and future needs of industry. Suppliers of radiation sources should not consider themselves in the cobalt-60, cesium-137, electron beam, or x-ray machine business per se but must recognize the existence of an irradiation industry and address the fact that the various sources can best be used in complementary ways to satisfy the needs of society. For example, rather than using highly energetic cobalt-60 to sterilize very low-density medical products, it may be prudent to employ electron beams for such purposes and apply the cobalt-60 to the task of irradiating higher density products such as food. Multiple sources, while in some sense complementary, will also serve competitively to ensure that adequate, economic radiation sources are available. Therefore, market forces would best determine which radiation sources would be required.

Question

Do you feel that your efforts to license the WESF capsules are being unnecessarily delayed?

Answer

Since July 1984, the NRC has indicated its willingness to expeditiously license both types of irradiators that would use WESF capsules. This would not require separate licensing of the capsules. This change in NRC procedures appears to be a wholly acceptable approach to the industry, and licensing of the WESF capsules may, at this juncture, be a moot point. It does not appear that unnecessary delays will be encountered.

Question

Would the DOE provide the HS&T Committee a report defining a cost-effective approach to maximizing the domestic availability of radioisotope source materials by optimizing DOE facilities? This report should identify costs, schedules, and quantities of radioisotopes as a function of time.

Answer

The DOE is presently conducting planning studies that evaluate a cost-effective approach to maximizing the domestic availability of radioisotope source materials by optimizing the use of available DOE facilities. The DOE would be happy to provide the results of this effort to the HS&T Committee when it is completed in FY 1985.

Question

To what extent is industry presently involved in the DOE food irradiation activities?

Answer

Industry is presently heavily involved in DOE's food irradiation activities. Technology transfer studies are being conducted by CH_2M Hill, a private engineering services firm under contract to DOE. Demonstration project efforts are being undertaken by Nuclear Packaging, Incorporated, and Foster Wheeler Energy Applications, Incorporated, for the transportable cesium irradiator. Both firms are currently performing design and fabrication tasks. A competitive selection of Rockwell International was recently made for design and fabrication of the cesium agricultural commodities irradiator. Assessments of feasibility of pork irradiation involve the National Pork Producers Council, a group representing the majority of all pork producers in the U.S. Consumer education and acceptance activities are being pursued in cooperation with the National Food Processors Association, a research-based group representing all major food processors in the U.S.

Question

With successful completion of those programs, how will industry follow to commercialization? What gamma ray sources do you anticipate at that time? How do you suspect residue will be disposed of? Please comment on applicable state licensing.

Answer

With the successful completion of the DOE R&D food irradiation activities, the technical and economic data base should be established for industry to evaluate ventures for various commodity application and alternate sites. In addition, the major institutional problems; e.g., licensing and FDA rulemaking, should be amenable to timely solutions. Policy questions; e.g., public acceptance of irradiated food commodities, should be defined to the point that should allow reasonable extrapolation to lead to answers with acceptable confidence limits.

The gamma ray sources available upon successful completion of DOE food irradiation activities will depend on market forces. For example, DOE could make future cesium-137 available on a full cost-recovery basis if industry deems this approach meets their needs. Similarly, the Advanced Test Reactor could be used to continue supplying small quantities of cobalt-60 contingent upon the continued interest of industry.

Residues from the cesium-137 irradiation activities will be disposed by DOE.

At the present time due to the newness of the cesium-137 licensing process, agreement States are deferring licensing activities to NRC.

Question

In the irradiation of fresh pork, you mention "DOE's intent to site" a facility for pork treatment at a university. What problems do you anticipate in such an activity?

Answer

A university site for the fresh pork irradiator is envisioned as the appropriate mechanism for technology transfer to the fresh pork packing industry. Such a site will allow the detailed investigation of all of the parameters (economic, technical, marketing, regulatory, etc.) attendant to implementation of irradiation technology and will insure that such data will be fully available and widely disseminated to the industry. A site at an existing meat packer would, in DOE's and the industry's view, raise concerns regarding proprietary operations of the meat-packing plant adjacent to the irradiator. More importantly, the risk of failure of the technology for reasons beyond the scope of the technology is greater at such a site where an irradiator is retrofitted to a packing plant. Prudent technology transfer dictates that the technology be proven in a setting of maximum flexibility so that options can be pursued and problems identified and corrected without jeopardy to the balance sheet of one specific company. In addition, the terms of the DOE Request for Proposal require that the university possesses the wide range of research capabilities (veterinary medicine, meat science, biology, chemistry, economics, consumer acceptance, etc.) which can be utilized in assessing the commercial feasibility and specific applicability of food irradiation technology to the fresh pork-packing industry.

At this time, a Request for Proposals for interested universities is being prepared by DOE for release this fall. No insurmountable problems are anticipated in this process.

Question

In the interaction you mention between DOE and the Nuclear Regulatory Commission relative to the determination of specific adaptable irradiator designs and conditions, do you anticipate a standard modular unit? To what extent has the industrial sector been active in this DOE-NRC dialogue?

Answer

The DOE-NRC dialogue to date has involved the basic safety issues of cesium-137 encapsulated in the standard WESF capsule over a range of parameters that exceed those that would be encountered in anticipated irradiator designs. NRC in reviewing two types of industrial irradiator designs to date has placed limits on allowable conditions that can be encountered in acceptable irradiator designs. NRC has mandated a followup cesium capsule testing program to be conducted by DOE for each of two types of industry irradiator designs to confirm that actual irradiator conditions do not adversely impact capsule integrity. DOE has made available to industry and to the NRC the basic safety information required to use the capsules in various industrial irradiator designs. It would be inappropriate for DOE to participate directly in the dialogue between NRC and industry licensees unless requested by the NRC as a technical resource.

While a standard modular unit design of gamma irradiator would ease NRC licensing burdens, a standard modular unit is not anticipated in the near future.

Question

Assuming that spent nuclear fuel will never be reprocessed, where will cesium-137 come from?

Answer

If it is assumed that spent nuclear fuel will never be reprocessed, there are two sources of cesium 137; namely,

(1) the 250 million curies of cesium-137 in current and future inventories of DOE defense waste, and

(2) cesium-137 produced by other countries that process spent nuclear fuel; for example, France and England.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OCT 12 1984

The Honorable Marilyn Lloyd
Chairman, Subcommittee on Energy Research
and Production
Committee on Science and Technology
United States House of Representatives
Washington, DC 20515

Dear Madam Chairman:

In response to your letter of September 20, 1984 I am pleased to supplement the record of the July 26, 1984 hearing on the Status of the Technical Infrastructure Required to Support Domestic Food Irradiation. My response to the list of questions submitted with your letter is attached.

Sincerely,

R.R. Chappell
for Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety

Enclosure: As stated

RESPONSES TO ADDITIONAL QUESTIONS

1. QUESTION:

Does the chemical form of the Cesium in DOE's current capsules -- Cesium Chloride (CsCl), which is a liquid and is also very soluble in water -- present any safety problems? How do the main safety concerns in licensing use of a Cs-137 radiation source compare to the concerns in licensing a Cobalt-60 source?

ANSWER:

The cesium chloride (CsCl) contained in the DOE's capsules is a solid. The main safety issues related to these capsules are potential attack by the cesium salt on capsule containment and solubility if released. The DOE has conducted corrosion examinations to confirm the adequacy of the capsule to maintain its integrity and is conducting further tests to determine the effects of thermal cyclings, as would be encountered in use of the capsules in a wet-storage, dry irradiation operation, on the capsule. If the test data demonstrate containment integrity, we believe that the capsules will be adequate for use in irradiators.

The Cobalt-60 contained in currently used capsules is in the form of solid metal seeds which are only slightly soluble in water. The Cobalt-60 capsules have been used several years in irradiators and have a good record of integrity.

Regardless of capsule integrity, backup systems are required to detect leakage. Due to the very high solubility of CsCl compared to metallic Cobalt-60, special procedures are contemplated to manage leakage in the unlikely event that it occurrs.

The safety considerations for operation of an irradiator containing either Cesium-137 or Cobalt-60 are the same.

2. QUESTION:

Would it not be prudent from a safety concern to require the same standards for maintaining an operating license for a cobalt wet storage irradiator?

ANSWER:

Once the integrity and adequacy of the capsules used in an irradiator have been demonstrated, the safety considerations are essentially the same for irradiators containing either cesium chloride or cobalt metal in the capsules. As noted above, the management of CsCl leakage in the event that it occurs requires some additional precautionary procedures due to its solubility.

3. QUESTION:

What manner of waste disposal is currently required for large radiation sources? Do you have an idea of what the cost of disposal is (or might be) on a cost per curie of radiation basis? What process does the NRC use to assure that radiation sources will be disposed of properly?

ANSWER:

Most of the large irradiators in the United States use Cobalt-60 sources purchased from Atomic Energy Canada Limited (AECL). Under present arrangements, most of these sources are replaced and the spent sources are reclaimed by AECL. Cesium chloride sources in the form of WESF capsules are supplied by DOE. DOE has stated that it will take back spent capsules for storage. Requirements for disposal of waste by an individual licensee are set forth in the Commission's regulation 10 CFR Part 20, "Standards for Protection Against Radiation," for sources of the type used in irradiators. The regulation permits transfer only to persons specifically licensed to possess the sources such as operators of commercial land burial facilities. The operations of a commercial waste burial ground are governed by the Commission's Regulation 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste," or equivalent regulations by an Agreement State.

Charges by commercial land burial facilities for disposal of wastes are based on package volume and the extent of special handling. For waste of low activity current charges at burial grounds range from $17.00 to $30.00 per cubic foot of package volume. Based on our discussions with a burial ground operator, the cost of disposal of very large sources (about 30,000 Ci) could be as high as $3000 per cubic foot of package volume.

4. QUESTION:

Does the NRC know the current location and condition of all radiation sources that are in the United States? What about sources fabricated in the United States and exported to other countries? Are you confident that the situation that recently occurred in Mexico -- where a cobalt radiation source was relegated to a junkyard and wound up exposing numerous individuals to excessive radiation levels -- was a fluke and is not likely to happen again? Has the NRC taken any actions that could prevent another such occurrence?

ANSWER:

The specific licenses issued by the NRC specify the radiation sources which may be possessed by licensees and specify the location at which the sources may be used. Specific licensees who distribute radiation sources to general licensees are required to report the name and location of persons to whom the sources are sent. Although the NRC does not know the condition of radiation sources at any given time, licenses which provide for possession and use of the sources require periodic leak testing of them. If there is any leakage of radioactive material from a source, the licensee is required to report the leakage to the NRC and take immediate steps to correct the problem. The NRC conducts periodic inspections of persons licensed to possess radiation sources to determine if the licensee's program is in compliance with NRC regulations and the terms and conditions of the licenses.

With respect to radiation sources fabricated in the United States and exported to the other countries, the NRC does not have knowledge of the location and condition of the sources. The NRC staff is analyzing the issues related to notification of foreign governments of the export of radioactive sources to persons in foreign countries.

Although we believe the incident which occurred in Mexico to be a unique situation, the following actions are being taken to minimize other occurrence or the effects of such an occurrence.

1. A study under contract with Aerospace Corporation has been initiated to assess the feasibility of detecting unauthorized radioactive material accidentally contained in items that enter the United States through commercial import channels.

2. Radiation detection instruments have been provided to each of the 22 U.S. Customs port of entry locations along the U.S./Mexico border and Customs agents have been instructed in the use of the instruments.

3. The NRC is developing plans to provide prompt response to incidents such as the Mexican incident. The response plan will incorporate interactions with other Federal agencies and State governments.

RESPONSES TO MINORITY QUESTIONS

1. QUESTION:

What amount of effort is necessary to reach an agreement with a state relative to material irradiation? How soon do you think the remaining 23 states will reach such agreement with NRC?

ANSWER:

Section 274 of the Atomic Energy Act, as amended, provides a mechanism which permits states to assert regulatory authority over certain categories of radioactive materials - byproduct materials (radioisotopes), source materials (the raw materials of Atomic Energy) and small quantities of special nuclear material. Irradiators typically use byproduct materials. The criteria that states wishing to enter into such agreements must meet are provided in a Commission Policy Statement published in the Federal Register (46 FR 7540, January 23, 1981; 46 FR 36969, July 16, 1981; and 48 FR 33376, July 21, 1983). After an agreement is signed, the Act requires periodic reviews by NRC of Agreement States programs. Guidelines for this purpose have been issued by the Commission as a Policy Statement (see 46 FR 59341, December 4, 1981).

The amount of effort needed to enter into an agreement is a function of several variables including the scope of the proposed agreement, the number of NRC licenses that will be transferred to the state and the amount of preparatory work that is needed. Preparatory work includes drafting and enactment of enabling legislation, recruitment and training of staff to carry out the program, drafting and promulgation of regulations, and development of administrative and technical procedures. Supporting documentation for the Governor's request for the agreement showing that the program will meet the criteria must also be prepared. Typically, once a decision is made to seek status as an Agreement State, preparations for an agreement take one to two years.

Whether or not a state seeks an agreement is a matter of choice for the state. At the present time, NRC is negotiating agreements with Iowa and Illinois. Pennsylvania is actively working toward an agreement. While timeframes have not been firmly set, we believe that agreements with Iowa and Illinois are possible by late 1985 or early 1986. Other states are presently examining the possibility of entering into an agreement; these include Virginia, Massachusetts and Wisconsin.

2. QUESTION:

In your experience, what is the public perception of food irradiation?

ANSWER:

We have not dealt with the general public on the matter of food irradiation. The Public Health Service, Department of Health and Human Services, published a proposal in the Federal Register on February 14, 1984, on the use of radiation sources for the treating of food and is analyzing public response on this issue.

3. QUESTION:

If the individual states are the irradiation regulators, what role do you anticipate for NRC relative to that technology in the future?

ANSWER:

Irradiators are licensed by both the NRC and the Agreement States. The NRC has offered to provide technical assistance to Agreement States in the review of applications for large irradiators. The NRC has dealt directly with the Department of Energy on the matter of the use of the DOE Cesium-137 capsules in irradiators. The regulatory position developed by the NRC, on the basis of DOE experience and our licensing practices, is provided to the Agreement States for their adoption.

For future technology, which might be licensed by an Agreement State, we anticipate analyzing the technology for safety considerations and providing guidance as might be appropriate.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 12 1984

The Honorable Marilyn Lloyd
Chairman, Subcommittee on Energy Research
and Production
Committee on Science and Technology
Washington, D.C. 20515

Dear Ms. Lloyd:

This is in response to your letter of September 20, 1984, to Dr. Sanford Miller, Director, Center for Food Safety and Applied Nutrition, requesting responses to your questions to supplement the record of the July 26, 1984 hearing on the Status of the Technical Infrastructure Required to Support Domestic Food Irradiation.

We have enclosed our responses to your questions.

Sincerely yours,

Robert C. Wetherell Jr.

Robert C. Wetherell, Jr.
Associate Commissioner
for Legislation and Information

Enclosure

ADDITIONAL QUESTIONS FOR DR. SANFORD A. MILLER

A. The law currently requires that irradiation is to be regarded as an additive and therefore subject to all of the applicable conditions that would apply to the many chemicals used in foods. Has that determination unnecessarily impeded the development of food irradiation in this country?

No, we do not think so. The law only requires that irradiation of foods be shown to be safe before foods are irradiated commercially.

B. Can you describe the problems you've found regarding the toxicology studies that have been conducted on irradiated food?

We have reviewed over 400 studies conducted on irradiated foods. The deficiencies in these studies fall into two general categories, (1) problems associated with diet, and (2) inadequate experimental design. Some examples of these categories are presented below:

1. Dietary Problems

   a. General dietary deficiency (vitamin, mineral or protein);

   b. Restricted food intake: and

   c. Unpalatable diet (e.g., increased peroxidation of oils).

2. Inadequate Experimental Design

   a. Inadequate control diet;

   b. "Replicate" experiments;

   c. Too few animals/sex/group, use of one sex, or numbers of animals were not reported;

   d. Combining data such as "total tumors," which is currently considered inappropriate;

   e. Inadequate presentation of the final report, or insufficient data for evaluation (e.g., only a summary was presented);

   f. Addition of antioxidants such as BHT or ethoxyquin to diet either before or after irradiation;

   g. Insufficient recovery time for female animals between breedings in a reproduction study;

   h. Lack of random selection of animals for groups;

i. Questionable culling practices, and/or sibling mating, in reproduction studies;

j. Inadequate histopathology;

k. Use of animals too old for breeding purposes;

l. Addition of extra animals in the middle of experiments; and,

m. Inadequate length of time for a study (e.g., carcinogenicity).

3. Other deficiencies include

a. Irradiation dose not reported;

b. No non-irradiated diet controls;

c. Administration other than oral;

d. Type of food administered not reported; and,

e. Studies done by laboratories whose results could not be reproduced or laboratories that have been convicted for fraudulent data.

C. Could you characterize the commercial interest in food irradiation for us based on the comments that you have received on your proposed regulation? Have you had many requests for information from companies that may be interested in entering the irradiation business? Have any large food processing concerns expressed an interest?

About 4 percent of the comments on our proposal are from commercial interests (94 percent from consumers, 2 percent other), which includes the radiation processing industry, the food industry, and the investment industry. In general, all industry components would like to have the authority to choose whether they irradiate foods. Several companies, including large companies, have expressed interest, but we do not know whether their interest is exploratory or actual commitment.

D. The great majority of the health research on food irradiation has been done on foods irradiated with Cobalt-60 (Co-60). Is that body of research applicable to irradiation with Cs-137?

Yes, both radionuclides are sources of gamma radiation and have energy levels too low to induce radioactivity. The available data indicate that the effects of gamma radiation are independent of source as long as the source energy is sufficiently low.

E. What technological developments are required to adequately deal with the unidentified chemicals formed within irradiated foods?

First, one must recognize that at low concentrations most chemical components of foods are often not identifiable. This is true of unprocessed foods and cooked foods as well as irradiated foods. Furthermore, because of inherent limitations of analytical chemistry and finite resources, there likely will always be some unidentified chemicals in our foods.
To adequately deal with this issue, one must gain confidence that the total amount and general toxicity of unknown chemicals is too low to be of concern. As the radiation dose increases and the amount of irradiated food in the diet increases, the amount of unidentified chemicals consumed because of the irradiation process increases. Thus, one needs a bench mark for deciding when more information is needed. We have tried to do this with our proposal for limited uses of low levels of irradiation.

In general, increased knowledge of food chemistry from all kinds of processing is essential to better deal with the uncertainty from unidentified chemicals. Such increased knowledge would probably not result from any single technological development but from sustained basic research into food chemistry.

F. Does the existing technology provide the necessary ability to calibrate and monitor machine dosage rates consistent with allowable limits?

Yes, at this time we see no problem from a regulatory standpoint.

MINORITY QUESTIONS

1. We are told that American industry is using irradiation for the control of insect infestation of wheat and wheat products, although FDA approved such usage in 1963. Why do you suppose this is not being done?

We do not know. The alternative methods of using chemical pesticides may be cheaper. In any case, we believe the food industry can answer this question better than FDA.

2. Both you and USDA mentioned data on radiation sterilization of chicken meat. What period of time will be necessary for proper review of these data?

We received some 50,000 pages of data on radiation-sterilized chicken meat from USDA this spring. We expect to take a year to complete our review.

3. To what extent should the FDA be involved in a public education program relative to food irradiation?

First, we must distinguish between a public education program that is neutral and one that is promotional.

We believe that FDA should explain its actions to the public in all areas of its responsibilities including the safety of food irradiation. FDA has sent several thousand letters to persons interested in such issues, has published articles in its consumer magazine, and has conducted several consumer hearings around the country. We believe FDA's education efforts should be commensurate with consumer interest, however, and should not be disproportionate to activity in other areas of consumer interest.

We believe that FDA should not be involved in any activity that could be considered promotional. As a regulator of all food processing, the Agency should not take a stand that would promote one processing method or segment of industry over another, except where public health so requires. We believe the industry that desires to irradiate food should do the promotional activity.